



The effects of Infant Behavioral Sleep Interventions on Maternal Sleep, mood, and Infant Sleep: A Randomized Control Trial

Journal:	<i>Journal of Sleep Research</i>
Manuscript ID	JOSR-20-730.R2
Manuscript Type:	Regular Research Paper
Date Submitted by the Author:	n/a
Complete List of Authors:	Rouzafzoon, Mozghan; Tehran University of Medical Sciences Farnam, Farnaz; Tehran University of Medical Sciences, Khakbazan, Zohre; Tehran University of Medical Sciences
Keywords:	Behavioral Intervention, Infant Sleep, Sleep Quality, Postnatal Depression, Randomized Control Trial, Iran

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The effects of Infant Behavioral Sleep Interventions on Maternal Sleep, Mood and Infant Sleep: A Randomized Control Trial

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Short title: Infant behavioral sleep intervention

Total number of words: 3389

Total number of references: 40

Funding/Support: This study was supported by the Tehran University of Medical Sciences. Tehran University of Medical Sciences (Grant No. 97-02-28-38087)

Conflict of Interest Disclosures: The authors have no conflicts of interest relevant to this article to disclose.

Role of Funder/Sponsor: The project approved by Tehran University of Medical Sciences

Clinical trial Registration: Registered by Iranian Registry of Clinical Trial (IRCT), Number: 20120609009975N5.

Data Sharing Statement: The data that support the findings of this study are available from corresponding author upon reasonable request.

Author Contributorship

Mozhgan Rouzafzoon, conceptualized and designed the study, designed the data collection process, collected data, carried out the initial analyses, drafted the initial manuscript reviewed and approved the manuscript

Prof. Farnaz Farnam conceptualized and designed the study, designed the data collection process, carried out the initial analyses, drafted the initial manuscript reviewed and approved the manuscript

Prof Zohra Khakbazan conceptualized and designed the study, approved the manuscript

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3 All authors approved the final manuscript as submitted and agree to be accountable for all
4 aspects of the work.
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7 **Abbreviations:** **BSI:** Behavioral Sleep Intervention; **NTS:** Nighttime sleep period; **LSRS:**
8 Infant longest self-regulated sleep; **NTAS:** Nighttime awakenings with signals; **ME:** Middle
9 East; **IRCT:** Iranian Registry of Clinical Trials; **PSQI:** Pittsburgh Sleep Quality Index; **EPDS:**
10 Edinburgh Postnatal Depression Scale.
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12 **Acknowledgment**

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14 - This work was supported by Tehran University of Medical Sciences (Grant No. 97-02-28-
15 38087) and Ethic committee reference number: IR.TUMS.FNM.REC.1397.036.
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18 The research team is very grateful of Dr. Mehdi Yaseri and Dr Maryam rad for consulting about
19 analysis; Dr. Elahe Amini for developing content of interventions and Dr Jodi Mendel for helpful
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The effects of Infant Behavioral Sleep Interventions on Maternal Sleep and Mood and Infant Sleep: A Randomized Control Trial

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Abstract:

Infant sleep problems are one of the first challenges of parents, negatively influencing infants and mothers. This study examined the effects of preventive Behavioral Sleep Intervention (BSI) on infant sleep patterns, maternal sleep quality, and depression. A randomized multicenter clinical trial was conducted in 82 mothers and their 2-4 months infants in Iran from August 2018 to April 2019. The intervention group received BSI, which included one individual 90 minutes class session, booklet, voice messages, and follow-up calls, while the control group received training on general infant safety. Details of infant sleep, maternal sleep quality, and Postnatal depression were measured through the sleep diary, Pittsburgh Sleep Quality Index, and Edinburgh Postnatal Depression Scale, respectively, before and eight weeks after the training. In the intervention group, both mean infant Nighttime Sleep period (NTS) and Infant Longest Self-regulated Sleep period (LSRS) were 81 minutes longer than the controls ($P < 0.001$). By improvement of 160 minutes, the mean infant bedtime was decreased to 22:20 in the intervention group, substantially earlier than the controls (00:30). The mean infant Nighttime Awakenings with Signals (NTAS) didn't significantly change (2.6 and 2.5 times in the intervention and control groups, respectively). The intervention led to a significant improvement in maternal sleep quality and depression ($P > 0.05$).

This study acknowledges the positive effects of an early preventive infant BSI on infant sleep, maternal mood, and maternal sleep. Our results also imply the importance of considering the sleep patterns differences and cultural-based intervention's design.

Keywords: Behavioral Intervention; Infant Sleep; Sleep Quality; Postnatal Depression; Randomized Controlled Trial; Iran.

Introduction

Infant sleep problems are prevalent within the first few months after birth (Bayer, Hiscock, Hampton, & Wake, 2007). Approximately 46% of parents complain about infant sleep problems (Hiscock & Wake, 2001, 2002). Parent-reported infant sleep problems in 0-23 months babies have a prevalence range of 75.93%, 31.6%, 24.4%, and 22.6% in China, Australia, the United States, and the U.K., respectively (Mindell, Sadeh, Wiegand, How, & Goh, 2010). Mothers complaining about their infant sleep problems are more likely to have low sleep quality (Bayer et al., 2007). However, enhanced parental knowledge about infant sleep leads to better mood and sleep quality (Hall et al., 2015; Smart & Hiscock, 2007). Moreover, maternal complaints about infant sleep problems have a significant relationship with increased postnatal depression (H. Hiscock & Wake, 2001; Sadeh, Tikotzky, & Scher, 2010). Infant sleep problems negatively influence maternal sleep and mood as well as child's cognitive-behavioral development and increase the likelihood of future overweight (Alamian, Wang, Hall, Pitts, & Ikekwe, 2016; Schmid, Schreier, Meyer, & Wolke, 2010; Touchette, Petit, Tremblay, & Montplaisir, 2009). Some even suggest a link between sleep and weight gain even in the first month of life (Tikotzky et al., 2010).

Most changes in various aspects of sleep occur during the first 3 months after birth. Preventive measures and [Behavioral Sleep Intervention \(BSI\)](#) may affect mothers and infants. Without an overall consensus on the effect of BSI on infants, some consider it beneficial and necessary from the first months (Crichton & Symon, 2016; Henderson, France, & Blampied, 2011), while others doubt the effectiveness of these interventions for infants younger than six months (Douglas & Hill, 2013). There is evidence showing the positive effects of BSI on maternal mood (Crichton & Symon, 2016; Hall et al., 2015; Harriet Hiscock et al., 2014; Mindell et al., 2011), as well as no effects (Douglas & Hill, 2013; Galland et al., 2017; Mindell, Lee, Leichman, & Rotella, 2018; Owais, Chow, Furtado, Frey, & Van Lieshout, 2018; Stremmler et al., 2013). However, few RCTs have been performed to evaluate infant BSI's effectiveness, especially in infants younger vs. older than six months (Kempler, Sharpe, Miller, & Bartlett, 2016; Reuter, Silfverdal, Lindblom, & Hjerm, 2020).

Although assessing the effects of BSI entails conducting studies in different societies and cultures, most studies are designed based on the western family structure (Etherton, Blunden, &

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3 Hauck, 2016; Jenni & O'Connor, 2005). Despite the high prevalence of sleep problems in
4 mothers and infants in the Middle East (M.E.), [there is a lack of information in this area, and this](#)
5 [can be the highlighted necessity for a higher level of attention to this area by the researchers and](#)
6 [healthcare staffs](#) (Mindell, Lee, & Sadeh, 2017).
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11 [In Iran, like many other Asian countries, we encounter a dearth of infant sleep researches.](#) To
12 understand infant sleep patterns in Iran, first, we should look at Iranian families' sleep routines.
13 In Iran, most mothers are housewives, and they usually have a late wake time around 10 am, and
14 naturally, their infants sleep more in the morning and afternoon. On the other hand, most men
15 come back home very late (around 8 pm or even later) and play with babies after this time.
16 Besides, most small family gathering parties (a widespread activity in the Iranian daily schedule)
17 hold at night, and babies are one of the most important members of these parties. In such a noisy
18 environment, babies are full of excitement, and consequently, they cannot sleep well, and most
19 of the time, babies awake till parent bedtime. Considering the average Iranian adult bedtime
20 (around 23:00) (Hamshahri Media Research and Studies Center, 2008), children also often have
21 a late bedtime like most Asian and M.E. countries (Mindell et al., 2017; Mindell et al., 2010).
22 Meanwhile, parents themselves are not happy with these babies' sleep habits, and in fact, lack of
23 knowledge about positive sleep behaviors seriously influences maternal health and couples'
24 satisfaction (Raisi, Farnam, & Merghati-khoei, 2019). However, we do not have any education
25 about infant sleep in Iran's health system that could mainly be due to the absence of research
26 about infant sleep. In one of the rare studies on 1-2 years old children, 71% of Iranian toddlers
27 sleep after 22:00, 62% had undesirable sleep habits, and 25% had an experience of at least three
28 times awakening at night (Nafeiy, Shakiba, & Kashavarzian, 2009).
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43 Accordingly, as one of the first RCTs on BSI in Iran and M.E. countries, the present study
44 aimed to examine the effect of infant BSI on maternal sleep quality as a primary outcome and
45 infant sleep quantity and maternal postnatal depression as secondary outcomes. This paper
46 reports only some of the project findings.
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51 **Methods**

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54 This multicenter parallel-controlled randomized clinical trial was conducted in Tehran, Iran,
55 from August 2018 to April 2019. Blinding the study wasn't possible, given the educational
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3 nature of the intervention. The requisite scientific and ethical permissions were obtained from the
4 Tehran University of Medical Sciences and the Iranian Registry of Clinical Trials (IRCT)
5
6 Number: 20120609009975N5.
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8 9 **Participants**

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13 After explaining the study and its purposes, written informed consents were obtained from 92
14 eligible mothers tending to participate in the research. Maternal inclusion criteria included
15 deciding to not returning to work within the next ten weeks, not having a previously diagnosed
16 sleep disorder or uncontrolled chronic disease, not taking sleeping pills or antidepressants, not
17 addicted to alcohol and drugs (self-report), and no history of stillbirth or miscarriage. Infant
18 inclusion criteria included being the first or second child in the family, singleton, the age of 2-4
19 months old, healthy without abnormalities, birth at the age of 37 weeks and above, birth weight
20 of ≥ 2500 g, and without a history of hospitalization in NICU. Maternal exclusion criteria
21 included mothers who needed any hospitalization for more than three days, surgery, diagnosis of
22 sleep disorders or depression, and taking sleeping pills or antidepressants all through the study.
23 Infant exclusion criteria included infants requiring surgery, hospitalization for more than three
24 days, or having growth disorders (according to their growth chart) after enrollment and during
25 the project. It should be mentioned since mother and infant are considered one participant (unit
26 of analysis), excluding one of them meant omitting a unit.
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38 **Randomization**

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41 Out of 33 health centers affiliated with the Tehran University of Medical Sciences, six centers
42 were randomly selected. We assessed 431 mothers, and finally, 92 mothers were eligible and
43 intended to participate in our study. Then, they randomly divided into two groups of intervention
44 (sleep training) and control (general safety) (both $n=46$) using a computer-generated random
45 number sequence created by an independent statistician. Each mother and her infant considered
46 as one research unit. In each center, approximately 15-16 persons attended the study. The Group
47 assignment was concealed in a sealed opaque envelope (Figure 1).
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Interventions

Mothers of both groups received pretest questionnaires and infant sleep diary when referred for routine 2-4-month infant care, along with an explanation of diary completion. After seven days, we collected the completed sleep diary and other pretest questionnaires. The educational intervention was held as an in-person individual class session for mothers in both groups by M.R., one of the research team members. In the intervention group, we provided a 90 minutes class about infant BSI according to their age and a booklet containing similar instructions aimed at informing mothers and developing infant's independent sleep skills. Some of these instructions were about making a difference between day and night for the baby, avoiding digital instrument and T.V in the evening, using the daylight, and doing more active games in the morning, dimming the lights, and reducing noises of the house environment in the afternoon, knowing positive and negative sleep onset associations, having a consistent bedtime routine every night, maintaining consistent bedtime, considering a constant place for infant sleep, putting the infant in bed, awake but drowsy and using dream feed technic (table 1).

In the control group, we provided a 30-minute training session on general infant safety along with an educational pamphlet. During the eight weeks of follow-up, the researcher used weekly phone calls, text, and voice messages to communicate with the intervention group, while the control group received a phone call every other weak. To prevent the sample contaminations, we scheduled classes on different days for the two groups. Besides, mothers were asked not to share the information obtained with other mothers until the end of the study. Eight weeks after the educational intervention, the post-test infant sleep diary was again completed for four days and collected with other post-test questionnaires.

Outcome measurements

Demographic characteristics were designed with 13 questions on age, mothers' educational level, adequacy of the family monthly income, Childbirth method, Infant gestation age, gender, birth age and weight, birth order, breastfeeding status, room sharing, bed-sharing, and family support.

Infant sleep Diary

Mothers completed the diary for at least four days a week, once before the study and again eight weeks after training. Each page represented a full day and night divided into 10-minutes parts. Consequences were measured by this tool included “Nighttime Sleep” duration (22:00 to 8:00) (NTS), the “Longest Self-regulated Sleep period” (LSRS), Nighttime Awakenings with a Signal (NTAS), and bedtime. Given the common habit of infant late bedtime in Iran, it was impractical to shift it from midnight to 20:00 (routine bedtime in many studies). Therefore we considered bedtime as 22:00 and “Nighttime Sleep” as 22:00 to 08:00.

Pittsburgh Sleep Quality Index (PSQI)

Maternal sleep quality over the past month was measured by the 9-item PSQI questionnaire, including seven dimensions of subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, use of sleep pills, and daytime dysfunction. Each dimension’s score ranged from 0-3, and the global score was from 0-21—a total score \geq of 5 indicating low sleep quality. The scale’s sensitivity and specificity were 89.6% and 86.5%, respectively (Bysse, Reynolds III, & Monk, 1989).

Edinburgh Postnatal Depression Scale (EPDS)

The 10-item EPDS was applied to measure postnatal depression with a score range of 0-30. A score \geq of 13 denoted a higher likelihood of developing depression. The scale sensitivity and specificity were computed as 86% and 78%, respectively (Cox, Holden, & Sagovsky, 1987).

Usefulness of strategies

At the end of the study, we asked the mothers in the intervention group to describe each of the eight main strategies trained as “easy to apply,” “hard to apply,” “helpful,” or “unhelpful” technique.

Statistical Analysis

92 participants were required to create at least two scores clinically significant difference in maternal sleep quality in this study, with 80% power, 95% confidence interval, and assuming a 15% dropout rate. Chi-square, Fisher's exact test, and independent t-test were used to homogeneity the two groups. The results at baseline and after eight weeks within each group were compared with the Paired t-test, and outcomes for two intervention and control groups were evaluated through an Independent t-test. Results expressed as the mean (standard deviation). Confounding variables were controlled by ANCOVA. A significance level of P-value<0.05 was considered. All analysis was conducted by the statistical software SPSS 25.0.

Results

82 persons continued their participation until the end of the study. (Figure 1)

Baseline data

The average ages of mothers and infants were 29.6 years and 3.0 months, respectively. 73.1% of mothers had an academic degree. Statistics on delivery modes showed a significant difference between the two groups at the baseline. It didn't seem that this factor influences our results because our intervention started at least 70 days after delivery. 69.5% of infants were exclusively breastfed, with 97.5% and 14.6% of them had the experience of room-sharing and bed-sharing with parents, respectively (Table 2).

In the beginning, all infants had about an average of 3.79h "Longest Self-regulated Sleep" and 7.35h "Nighttime Sleep." Surprisingly, in our study, 94% of babies' bedtime at baseline was about 11 pm or later, and the range of it was between 10:30 pm and 4:00 am. In both groups, infants woke up about 2.75 times at night and called for their mothers.

Eight weeks after the training

The intervention group infants showed significant positive changes in "Longest Self-regulated Sleep," "Nighttime Sleep," and "Bedtime" (P<0.001). Without any significant difference, "Nighttime Awakenings with a Signal" was improved in both groups over time (Table 2).

The mean “Longest Self-regulated Sleep” values were $4.3\text{h} \pm 1.1\text{ h}$ and $3.0 \pm 0.7\text{h}$ in the intervention and control groups, respectively ($P < 0.001$). In the intervention group’s infants, the mean “Nighttime Sleep” also increased significantly ($8.8 \pm 0.5\text{h}$) compared with the controls ($7.5 \pm 0.8\text{h}$) ($P < 0.001$). Changing from 1:00 am to 22:20, the mean “bedtime” improved significantly in the intervention group’s infants, while it altered from 00:52 am to 00:26 am in the control group ($P < 0.001$).

“Nighttime Awakenings with a Signal” numbers decreased slightly over time in both groups. In the intervention group from 3.0 ± 2.2 time to 2.5 ± 0.9 and the control group from 2.9 ± 1.3 to 2.6 ± 1.1 . However, we didn’t find a significant difference between the two groups ($P = 0.64$) (Table 3).

Over time, the mean score of maternal sleep quality changed from 10.9 ± 2.9 to 8.9 ± 3.1 in the intervention group, as well as 9.5 ± 3.5 to 9.6 ± 2.6 in the control group, indicating a significant improvement in sleep quality of the mothers ($P > 0.05$). After the infant BSI, maternal depression was also decreased significantly ($P > 0.05$), with a depression score falling from 10.9 to 8.9 in the intervention group (Table 4).

In the final survey on the trained methods, 88% of the intervention group mothers described “maintaining a consistent bedtime for infants” as the most challenging technique, and about 66% of them found “having a consistent bedtime routine” as the next hard strategy (table 5).

Discussion

In this study, “Nighttime Sleep,” “Longest Self-regulated Sleep,” and “Bedtime” were significantly improved in the intervention group, while “Nighttime Awakenings with a Signal” didn’t change significantly. After training, maternal sleep quality and depression were also improved significantly in the intervention group.

After eight weeks of follow up, both “Nighttime Sleep” and “Longest Self-regulated Sleep” variables in the intervention group had an average of 1 hour and 21 minutes over the controls, probably caused by enhanced mothers’ awareness of infant sleep signals, consistent bedtime, and bedtime routine. Overall, this study’s baseline night sleep duration was 7 hours and 25 minutes, equaling the minimum age-favored average (Hirshkowitz et al., 2015). A systematic review in

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3 2013 indicated the significant effect of BSI on the increased infant sleep duration (Bryanton,
4 Beck, & Montelpare, 2013). In Mindell's study, they experienced around 36 minutes more
5 "Nighttime Sleep" (Mindell, Telofski, Wiegand, & Kurtz, 2009). However, Stremmer et al.
6 reported no significant changes in infant "Nighttime Sleep" at 6 and 12 weeks after BSI
7 intervention (Stremmer et al., 2013), which could result from early postpartum training.
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12 Because the average infant bedtime in Iran is highly different from the expert recommendations
13 (19 to 20:00 (Iglowstein, Jenni, Molinari, & Largo, 2003)), Maintaining a proper, consistent
14 infants' bedtime was among our study's principal aims. In the present study, the baseline
15 bedtime in the intervention group was at 1:00 am, even far later than the mean bedtime in the
16 M.E. countries (22:45) (Mindell et al., 2017). After the intervention, bedtime improved
17 significantly by 2 hours and 40 minutes. It should be mentioned that consideration of the ideal
18 bedtime (19:00-20:00) could have discouraged our mothers due to the significant difference that
19 it had from their infants' actual bedtime. Therefore, concerning cultural sleep differences in Iran,
20 such as late-night family gatherings and parents' late bedtime, we considered 22:00 as the
21 acceptable infant bedtime. As other researchers suggest (Etherton et al., 2016; Jenni &
22 O'Connor, 2005), considering the cultural characteristics in BSI designing can play a key role in
23 maternal participation and the intervention's success. It is worth noting that a proper bedtime is a
24 typical standard in other cultures, so the bedtime variable was not measured in most studies or
25 didn't significantly change after the intervention (Mindell et al., 2018; Mindell et al., 2009).
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38 In our research, "Nighttime Awakenings with a Signal" didn't significantly change in the two
39 groups following BSI. This finding was also repeated in the systematic reviews in
40 2013 (Bryanton et al., 2013; Symon, Marley, Martin, & Norman, 2005) and 2016 (Kempner et al.,
41 2016). The most critical factor influencing "Nighttime Awakenings with a Signal" seems to be
42 the type of intervention, especially the extinction techniques (Mindell, Kuhn, Lewin, Meltzer, &
43 Sadeh, 2006)³⁴. However, we didn't use it because these techniques aren't recommended to
44 apply in infants younger than six months (Meltzer & Crabtree, 2015).
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51 This study significantly improved maternal sleep quality following the intervention ($P < 0.04$).
52 Improving infant sleep and implementing maternal sleep hygiene strategies led to better maternal
53 sleep quality, but maternal sleep quality remained low, given the PSQI's cut point. It should be
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3 considered that due to numerous young baby awakenings, these mothers' sleep alteration can be
4 completely normal.
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7 Similar results were also reported in the other studies (Hall et al., 2015; Mindell et al., 2011),
8 emphasizing the importance of health care providers and the mother's family support during this
9 period due to low sleep quality. Even some other studies reported no changes in maternal sleep
10 quality after BSI. This finding may be due to providing the intervention just after delivery
11 (Galland et al., 2017; Stremmer et al., 2013) or late face-to-face contact with parents (Harriet
12 Hiscock et al., 2014).
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19 In our study, the score of postnatal depression was significantly decreased in the intervention
20 group compared with the control group. The depression is likely to be influenced by improved
21 infant sleep. In two studies by Hiscock et al., the overall score of maternal depression was
22 significantly improved after infant BSI (Harriet Hiscock et al., 2007; Harriet Hiscock et al.,
23 2014). It seems that the 2-month follow-up interval in Hiscock studies and the present study was
24 enough time for stabilizing infant sleep routines and reducing maternal depression. In contrast, in
25 Stremmer (Stremmer et al., 2006) and Mindell (Mindell et al., 2018) studies, BSI interventions did
26 not show any effects on maternal depression. It might be due to early postnatal education or short
27 follow-up.
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36 As one of the few RCTs on infant BSI in M.E. countries, the present research provided mothers
37 individual, in-person training sessions instead of group sessions with some difficulties such as
38 being time-consuming. Selecting infants merely younger than six months was one of the study's
39 strengths. For the reason that there is a lack of well-controlled studies in this age group (Douglas
40 & Hill, 2013; Kempler et al., 2016; Martins et al., 2018) for claiming possible positive effects of
41 BSI on infants under six months. To omit the impact of attention, the control group also received
42 training about infant safety. Compared to similar studies, our study's weaknesses include small
43 sample size, costly lengthy interventions, and collection of infant sleep information from
44 mothers' reports through the sleep diary (we didn't utilize objective tools such as actigraph).
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52 For future studies, we recommend that more research take place in countries with different
53 cultures to have a better understanding of any society's sleep pattern other than
54 western/European countries. Maybe some of these habits would be negative and should be
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3 changed, but the community looks at them as a culture and don't believe those can or should be
4 changed. We can find the benefits or harms of our sleep and parenting cultures through more
5 researches in different societies. Our other suggestion is to try just one behavioral intervention in
6 each study to understand which intervention can make infants' sleep habits or affect them due to
7 the highest variability in infant sleep at the age of under six months old.
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12 13 **Conclusion**

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16 An increase of 1 hour and 20 minutes in infant "Nighttime Sleep," as well as the improved
17 earlier bedtime by 2 hours and 40 minutes, was evidence of the positive effect of early infant
18 BSI.
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22 Promotion of maternal mood and sleep quality in this study could be an answer to the doubt
23 mentioned by Dr. Mindell(Mindell et al., 2010) and Dr.Sadeh (Sadeh et al., 2010), likely
24 usefulness of infant BSI in Asian or M.E. countries, where adult late bedtime is the dominant
25 pattern.
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30 Despite the significant improvement of maternal sleep quality after the intervention, it still
31 remained low. Consistent with some other studies (Hall et al., 2015Mindell et al., 2011), these
32 results implied the necessity of attention to mothers during this period.
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37 It should be noted that finding the best infant BSI requires considering each society's cultural
38 characteristics, entailing research, and determining infant and parental sleep characteristics.
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41 **Conflicts of Interest**

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44 The authors declare no conflict of interest.
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50 **Acknowledgment**

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53 - This work was supported by the Tehran University of Medical Sciences (Grant No. 97-02-28-
54 38087) and Ethic committee reference number: I.R.TUMS.FNM.REC.1397.036.
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3 The research team is very grateful to Dr. Mehdi Yaseri and Dr. Maryam rad for consulting about
4 analysis, Dr. Elahe Amini for developing the content of interventions, and Dr. Jodi Mindell for
5 helpful suggestions.
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For Peer Review

References:

Alamian, A., Wang, L., Hall, A. M., Pitts, M., & Ikekwe, J. (2016). Infant sleep problems and childhood overweight: Effects of three definitions of sleep problems. *Preventive Medicine Reports*, 4, 463-468. doi:<https://doi.org/10.1016/j.pmedr.2016.08.017>

Bayer, J. K., Hiscock, H., Hampton, A., & Wake, M. (2007). Sleep problems in young infants and maternal mental and physical health. *Journal of Paediatrics and Child Health*, 43(1-2), 66-73. doi:<https://doi.org/10.1111/j.1440-1754.2007.01005.x>

Bryanton, J., Beck, C. T., & Montelpare, W. (2013). Postnatal parental education for optimizing infant general health and parent-infant relationships. *Cochrane Database of Systematic Reviews*(11). doi:<https://doi.org/10.1002/14651858.CD004068.pub4>

Byssse, D., Reynolds III, C., & Monk, T. (1989). The Pittsburgh Sleep Quality Index (PSQI): a new instrument for psychiatric research and practice. *Psychiatry Research*, 28(2), 193-213.

Cox, J. L., Holden, J. M., & Sagovsky, R. (1987). Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. *The British Journal of Psychiatry*, 150(6), 782-786. doi:<https://psycnet.apa.org/doi/10.1192/bjp.150.6.782>

Crichton, G. E., & Symon, B. (2016). Behavioral Management of Sleep Problems in Infants Under 6 Months--What Works? *Journal of Developmental and Behavioral Pediatrics*, 37(2), 164-171. doi:<https://doi.org/10.1097/dbp.0000000000000257>

Douglas, P. S., & Hill, P. S. (2013). Behavioral Sleep Interventions in the First Six Months of Life Do not Improve Outcomes for Mothers or Infants: A Systematic Review. *Journal of Developmental & Behavioral Pediatrics*, 34(7), 497-507. doi:<https://doi.org/10.1097/DBP.0b013e31829cafa6>

Etherton, H., Blunden, S., & Hauck, Y. (2016). Discussion of extinction-based behavioral sleep interventions for young children and reasons why parents may find them difficult. *Journal of clinical sleep medicine: JCSM: official publication of the American Academy of Sleep Medicine*, 12(11), 1535. doi:<https://doi.org/10.5664/jcsm.6284>

Galland, B. C., Sayers, R. M., Cameron, S. L., Gray, A. R., Heath, A. L. M., Lawrence, J. A., . . . & Taylor, R. W. (2017). Anticipatory guidance to prevent infant sleep problems within a randomised controlled trial: infant, maternal and partner outcomes at 6 months of age. *BMJ Open*, 7(5), 11. doi:<http://dx.doi.org/10.1136/bmjopen-2016-014908>

Hall, W. A., Hutton, E., Brant, R. F., Collet, J. P., Gregg, K., Saunders, R., ... & Bhagat, R. (2015). A randomized controlled trial of an intervention for infants' behavioral sleep problems. *BMC pediatrics*, 15(1), 181. doi:<https://doi.org/10.1186/s12887-015-0492-7>

Hamshahri Media Research and Studies Center. (2008). Phone survey of the people of Tehran about sleep. Retrieved from <https://www.hamshahrionline.ir/news/63615>

1
2
3 Henderson, J. M., France, K. G., & Blampied, N. M. (2011). The consolidation of infants'
4 nocturnal sleep across the first year of life. *Sleep medicine reviews*, 15(4), 211-220.
5 doi:<https://doi.org/10.1016/j.smr.2010.08.003>

7
8 Hirshkowitz, M., Whiton, K., Albert, S. M., Alessi, C., Bruni, O., DonCarlos, L., . . .
9 Kheirandish-Gozal, L. (2015). National Sleep Foundation's sleep time duration
10 recommendations: methodology and results summary. *Sleep Health: Journal of the National*
11 *Sleep Foundation*, 1(1), 40-43. doi:<https://doi.org/10.1016/j.sleh.2014.12.010>

13
14 Hiscock, H., Bayer, J., Gold, L., Hampton, A., Ukoumunne, O. C., & Wake, M. (2007).
15 Improving infant sleep and maternal mental health: a cluster randomised trial. *Archives of*
16 *Disease in Childhood*, 92(11), 952-958. doi:<http://dx.doi.org/10.1136/adc.2006.099812>

17
18 Hiscock, H., Cook, F., Bayer, J., Le, H. N., Mensah, F., Cann, W., St James-Roberts, I. (2014).
19 Preventing early infant sleep and crying problems and postnatal depression: a randomized trial.
20 *Pediatrics*, 133(2), e346-e354. doi:<https://doi.org/10.1542/peds.2013-1886>

22
23 Hiscock, H., & Wake, M. (2001). Infant sleep problems and postnatal depression: a community-
24 based study. *Pediatrics*, 107(6), 1317-1322. doi:<https://doi.org/10.1542/peds.107.6.1317>

25
26 Hiscock, H., & Wake, M. (2002). Randomised controlled trial of behavioural infant sleep
27 intervention to improve infant sleep and maternal mood. *Brit Med J*, 324.
28 doi:[10.1136/bmj.324.7345.1062](https://doi.org/10.1136/bmj.324.7345.1062)

29
30 Iglowstein, I., Jenni, O. G., Molinari, L., & Largo, R. H. (2003). Sleep duration from infancy to
31 adolescence: reference values and generational trends. *Pediatrics*, 111.
32 doi:<https://doi.org/10.1542/peds.111.2.302>

33
34 Jenni, O. G., & O'Connor, B. B. (2005). Children's sleep: an interplay between culture and
35 biology. *Pediatrics*, 115(Supplement 1), 204-216. doi: <https://doi.org/10.1542/peds.2004-0815B>

36
37 Kempler, L., Sharpe, L., Miller, C. B., & Bartlett, D. J. (2016). Do psychosocial sleep
38 interventions improve infant sleep or maternal mood in the postnatal period? A systematic
39 review and meta-analysis of randomised controlled trials. *Sleep medicine reviews*, 29, 15-22.
40 doi:<https://doi.org/10.1016/j.smr.2015.08.002>

41
42
43 Martins, R. M., Oliveira, J. R., Salgado, C. C., Marques, B. L., Oliveira, L. C., Oliveira, G. R., . . .
44 . Ferreira, R. T. (2018). Sleep habits in infants: the role of maternal education. *Sleep Medicine*,
45 52, 138-144. doi:<https://doi.org/10.1016/j.sleep.2018.08.020>

46
47 Meltzer, L. J., & Crabtree, V. M. L. (2015). *Pediatric Sleep Problems: A Clinician's Guide to*
48 *Behavioral Interventions*: American Psychological Association.

49
50
51 Mindell, J. A., Du Mond, C. E., Sadeh, A., Telofski, L. S., Kulkarni, N., & Gunn, E. (2011).
52 Efficacy of an internet-based intervention for infant and toddler sleep disturbances. *Sleep*, 34(4),
53 451-458.B. doi:<https://doi.org/10.1093/sleep/34.4.451>

1
2
3 Mindell, J. A., Kuhn, B., Lewin, D. S., Meltzer, L. J., & Sadeh, A. (2006). Behavioral treatment
4 of bedtime problems and night wakings in infants and young children. *Sleep*, 29(10), 1263-1276.
5 doi:<https://doi.org/10.1093/sleep/29.10.1263>
6

7 Mindell, J. A., Lee, C., & Sadeh, A. (2017). Young child and maternal sleep in the Middle East.
8 *Sleep Medicine*, 32, 75-82. doi:<https://doi.org/10.1016/j.sleep.2016.11.011>
9

10 Mindell, J. A., Lee, C. I., Leichman, E. S., & Rotella, K. N. (2018). Massage-based bedtime
11 routine: impact on sleep and mood in infants and mothers. *Sleep Medicine*, 41, 51-57.
12 doi:<https://doi.org/10.1016/j.sleep.2017.09.010>
13
14

15 Mindell, J. A., Sadeh, A., Wiegand, B., How, T. H., & Goh, D. Y. (2010). Cross-cultural
16 differences in infant and toddler sleep. *Sleep Medicine*, 11(3), 274-280.
17 doi:<https://doi.org/10.1016/j.sleep.2009.04.012>
18

19 Mindell, J. A., Telofski, L. S., Wiegand, B., & Kurtz, E. S. (2009). A nightly bedtime routine:
20 impact on sleep in young children and maternal mood. *Sleep*, 32(5), 599-606.
21 doi:<https://doi.org/10.1093/sleep/32.5.599>
22
23

24 Nafeiy, Z., Shakiba, M., & Kashavarzian, F. (2009). The prevalence of sleep disorders in 1 to 2
25 year infants referring to Health Centers in Yazd, 2008-2009. *Toloo e Behdasht*, 8, 39-45.
26

27 Owais, S., Chow, C. H., Furtado, M., Frey, B. N., & Van Lieshout, R. J. (2018). Non-
28 pharmacological interventions for improving postpartum maternal sleep: A systematic review
29 and meta-analysis. *Sleep medicine reviews*, 41, 87-100.
30 doi:<https://doi.org/10.1016/j.smr.2018.01.005>
31
32

33 Raisi, F., Farnam, F., & Merghati-khoei, E. (2019). Understanding of the Iranian women of the
34 origin of their sexual dysfunctions: qualitative research. *Nursing and Midwifery Journal*, 17(1),
35 21-31(Persian). Retrieved from <http://unmf.umsu.ac.ir/article-1-3725-en.html>
36

37 Reuter, A., Silfverdal, S.-A., Lindblom, K., & Hjern, A. (2020). A systematic review of
38 prevention and treatment of infant behavioural sleep problems. *Acta Paediatrica*, 109(9), 1717-
39 1732. doi:<https://doi.org/10.1111/apa.15182>
40
41

42 Sadeh, A., Tikotzky, L., & Scher, A. (2010). Parenting and infant sleep. *Sleep medicine reviews*,
43 14(2), 89-96. doi:<https://doi.org/10.1016/j.smr.2009.05.003>
44

45 Schmid, G., Schreier, A., Meyer, R., & Wolke, D. (2010). A prospective study on the persistence
46 of infant crying, sleeping and feeding problems and preschool behaviour. *Acta Paediatrica*,
47 99(2), 286-290. doi:<https://doi.org/10.1111/j.1651-2227.2009.01572.x>
48

49 Smart, J., & Hiscock, H. (2007). Early infant crying and sleeping problems: a pilot study of
50 impact on parental well-being and parent-endorsed strategies for management. *Journal of*
51 *Paediatrics and Child Health*, 43(4), 283-290. doi:[https://doi.org/10.1111/j.1440-](https://doi.org/10.1111/j.1440-1754.2007.01060.x)
52 [1754.2007.01060.x](https://doi.org/10.1111/j.1440-1754.2007.01060.x)
53
54

55 Stremmer, R., Hodnett, E., Kenton, L., Lee, K., Weiss, S., Weston, J., & Willan, A. (2013). Effect
56 of behavioural-educational intervention on sleep for primiparous women and their infants in
57
58
59

1
2
3 early postpartum: multisite randomized controlled trial. *BMJ*, 346, f1164.
4 doi:<https://dx.doi.org/10.1136%2Fbmj.f1164>
5

6
7 Stremler, R., Hodnett, E., Lee, K., MacMillan, S., Mill, C., Ongcangco, L., & Willan, A. (2006).
8 A behavioral-educational intervention to promote maternal and infant sleep: a pilot randomized,
9 controlled trial. *Sleep*, 29(12), 1609-1615. doi:<https://doi.org/10.1093/sleep/29.12.1609>
10

11
12 Symon, B. G., Marley, J. E., Martin, A. J., & Norman, E. R. (2005). Effect of a consultation
13 teaching behaviour modification on sleep performance in infants: a randomised controlled trial.
14 *The Medical Journal of Australia*, 182(5), 215-218. doi:[https://doi.org/10.5694/j.1326-](https://doi.org/10.5694/j.1326-5377.2005.tb06669.x)
15 [5377.2005.tb06669.x](https://doi.org/10.5694/j.1326-5377.2005.tb06669.x)

16
17 Tikotzky, L., De Marcas, G., Har-Toov, J., Dollberg, S., Bar-Haim, Y., & Sadeh, A. (2010).
18 Sleep and physical growth in infants during the first 6 months. *Journal of sleep research*,
19 19(1-Part-I), 103-110. doi:<https://doi.org/10.1111/j.1365-2869.2009.00772.x>
20

21
22 Touchette, É., Petit, D., Tremblay, R. E., & Montplaisir, J. Y. (2009). Risk factors and
23 consequences of early childhood dyssomnias: New perspectives. *Sleep medicine reviews*, 13(5),
24 355-361. doi:<http://dx.doi.org/10.1016/j.smr.2008.12.001>
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The effects of Infant Behavioral Sleep Interventions on Maternal Sleep and Mood and Infant Sleep: A Randomized Control Trial

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Abstract:

Infant sleep problems are one of the first challenges of parents, negatively influencing infants and mothers. This study examined the effects of preventive Behavioral Sleep Intervention (BSI) on infant sleep patterns, maternal sleep quality, and depression. A randomized multicenter clinical trial was conducted in 82 mothers and their 2-4 months infants in Iran from August 2018 to April 2019. The intervention group received BSI, which included one individual 90 minutes class session, booklet, voice messages, and follow-up calls, while the control group received training on general infant safety. Details of infant sleep, maternal sleep quality, and Postnatal depression were measured through the sleep diary, Pittsburgh Sleep Quality Index, and Edinburgh Postnatal Depression Scale, respectively, before and eight weeks after the training. In the intervention group, both mean infant Nighttime Sleep period (NTS) and Infant Longest Self-regulated Sleep period (LSRS) were 81 minutes longer than the controls ($P < 0.001$). By improvement of 160 minutes, the mean infant bedtime was decreased to 22:20 in the intervention group, substantially earlier than the controls (00:30). The mean infant Nighttime Awakenings with Signals (NTAS) didn't significantly change (2.6 and 2.5 times in the intervention and control groups, respectively). The intervention led to a significant improvement in maternal sleep quality and depression ($P > 0.05$).

This study acknowledges the positive effects of an early preventive infant BSI on infant sleep, maternal mood, and maternal sleep. Our results also imply the importance of considering the sleep patterns differences and cultural-based intervention's design.

Keywords: Behavioral Intervention; Infant Sleep; Sleep Quality; Postnatal Depression; Randomized Controlled Trial; Iran.

Introduction

Infant sleep problems are prevalent within the first few months after birth (Bayer, Hiscock, Hampton, & Wake, 2007). Approximately 46% of parents complain about infant sleep problems (Hiscock & Wake, 2001, 2002). Parent-reported infant sleep problems in 0-23 months babies have a prevalence range of 75.93%, 31.6%, 24.4%, and 22.6% in China, Australia, the United States, and the U.K., respectively (Mindell, Sadeh, Wiegand, How, & Goh, 2010). Mothers complaining about their infant sleep problems are more likely to have low sleep quality (Bayer et al., 2007). However, enhanced parental knowledge about infant sleep leads to better mood and sleep quality (Hall et al., 2015; Smart & Hiscock, 2007). Moreover, maternal complaints about infant sleep problems have a significant relationship with increased postnatal depression (H. Hiscock & Wake, 2001; Sadeh, Tikotzky, & Scher, 2010). Infant sleep problems negatively influence maternal sleep and mood as well as child's cognitive-behavioral development and increase the likelihood of future overweight (Alamian, Wang, Hall, Pitts, & Ikekwe, 2016; Schmid, Schreier, Meyer, & Wolke, 2010; Touchette, Petit, Tremblay, & Montplaisir, 2009). Some even suggest a link between sleep and weight gain even in the first month of life (Tikotzky et al., 2010).

Most changes in various aspects of sleep occur during the first 3 months after birth. Preventive measures and Behavioral Sleep Intervention (BSI) may affect mothers and infants. Without an overall consensus on the effect of BSI on infants, some consider it beneficial and necessary from the first months (Crichton & Symon, 2016; Henderson, France, & Blampied, 2011), while others doubt the effectiveness of these interventions for infants younger than six months (Douglas & Hill, 2013). There is evidence showing the positive effects of BSI on maternal mood (Crichton & Symon, 2016; Hall et al., 2015; Harriet Hiscock et al., 2014; Mindell et al., 2011), as well as no effects (Douglas & Hill, 2013; Galland et al., 2017; Mindell, Lee, Leichman, & Rotella, 2018; Owais, Chow, Furtado, Frey, & Van Lieshout, 2018; Stremmler et al., 2013). However, few RCTs have been performed to evaluate infant BSI's effectiveness, especially in infants younger vs. older than six months (Kempler, Sharpe, Miller, & Bartlett, 2016; Reuter, Silfverdal, Lindblom, & Hjerm, 2020).

Although assessing the effects of BSI entails conducting studies in different societies and cultures, most studies are designed based on the western family structure (Etherton, Blunden, &

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3 Hauck, 2016; Jenni & O'Connor, 2005). Despite the high prevalence of sleep problems in
4 mothers and infants in the Middle East (M.E.), there is a lack of information in this area, and this
5 can be the highlighted necessity for a higher level of attention to this area by the researchers and
6 healthcare staffs (Mindell, Lee, & Sadeh, 2017).
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11 In Iran, like many other Asian countries, we encounter a dearth of infant sleep researches. To
12 understand infant sleep patterns in Iran, first, we should look at Iranian families' sleep routines.
13 In Iran, most mothers are housewives, and they usually have a late wake time around 10 am, and
14 naturally, their infants sleep more in the morning and afternoon. On the other hand, most men
15 come back home very late (around 8 pm or even later) and play with babies after this time.
16 Besides, most small family gathering parties (a widespread activity in the Iranian daily schedule)
17 hold at night, and babies are one of the most important members of these parties. In such a noisy
18 environment, babies are full of excitement, and consequently, they cannot sleep well, and most
19 of the time, babies awake till parent bedtime. Considering the average Iranian adult bedtime
20 (around 23:00) (Hamshahri Media Research and Studies Center, 2008), children also often have
21 a late bedtime like most Asian and M.E. countries (Mindell et al., 2017; Mindell et al., 2010).
22 Meanwhile, parents themselves are not happy with these babies' sleep habits, and in fact, lack of
23 knowledge about positive sleep behaviors seriously influences maternal health and couples'
24 satisfaction (Raisi, Farnam, & Merghati-khoei, 2019). However, we do not have any education
25 about infant sleep in Iran's health system that could mainly be due to the absence of research
26 about infant sleep. In one of the rare studies on 1-2 years old children, 71% of Iranian toddlers
27 sleep after 22:00, 62% had undesirable sleep habits, and 25% had an experience of at least three
28 times awakening at night (Nafeiy, Shakiba, & Kashavarzian, 2009).
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43 Accordingly, as one of the first RCTs on BSI in Iran and M.E. countries, the present study
44 aimed to examine the effect of infant BSI on maternal sleep quality as a primary outcome and
45 infant sleep quantity and maternal postnatal depression as secondary outcomes. This paper
46 reports only some of the project findings.
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51 **Methods**

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54 This multicenter parallel-controlled randomized clinical trial was conducted in Tehran, Iran,
55 from August 2018 to April 2019. Blinding the study wasn't possible, given the educational
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3 nature of the intervention. The requisite scientific and ethical permissions were obtained from the
4 Tehran University of Medical Sciences and the Iranian Registry of Clinical Trials (IRCT)
5 Number: 20120609009975N5.
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8 9 **Participants**

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13 After explaining the study and its purposes, written informed consents were obtained from 92
14 eligible mothers tending to participate in the research. Maternal inclusion criteria included
15 deciding to not returning to work within the next ten weeks, not having a previously diagnosed
16 sleep disorder or uncontrolled chronic disease, not taking sleeping pills or antidepressants, not
17 addicted to alcohol and drugs (self-report), and no history of stillbirth or miscarriage. Infant
18 inclusion criteria included being the first or second child in the family, singleton, the age of 2-4
19 months old, healthy without abnormalities, birth at the age of 37 weeks and above, birth weight
20 of ≥ 2500 g, and without a history of hospitalization in NICU. Maternal exclusion criteria
21 included mothers who needed any hospitalization for more than three days, surgery, diagnosis of
22 sleep disorders or depression, and taking sleeping pills or antidepressants all through the study.
23 Infant exclusion criteria included infants requiring surgery, hospitalization for more than three
24 days, or having growth disorders (according to their growth chart) after enrollment and during
25 the project. It should be mentioned since mother and infant are considered one participant (unit
26 of analysis), excluding one of them meant omitting a unit.
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38 **Randomization**

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41 Out of 33 health centers affiliated with the Tehran University of Medical Sciences, six centers
42 were randomly selected. We assessed 431 mothers, and finally, 92 mothers were eligible and
43 intended to participate in our study. Then, they randomly divided into two groups of intervention
44 (sleep training) and control (general safety) (both $n=46$) using a computer-generated random
45 number sequence created by an independent statistician. Each mother and her infant considered
46 as one research unit. In each center, approximately 15-16 persons attended the study. The Group
47 assignment was concealed in a sealed opaque envelope (Figure 1).
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Interventions

Mothers of both groups received pretest questionnaires and infant sleep diary when referred for routine 2-4-month infant care, along with an explanation of diary completion. After seven days, we collected the completed sleep diary and other pretest questionnaires. The educational intervention was held as an in-person individual class session for mothers in both groups by M.R., one of the research team members. In the intervention group, we provided a 90 minutes class about infant BSI according to their age and a booklet containing similar instructions aimed at informing mothers and developing infant's independent sleep skills. Some of these instructions were about making a difference between day and night for the baby, avoiding digital instrument and T.V in the evening, using the daylight, and doing more active games in the morning, dimming the lights, and reducing noises of the house environment in the afternoon, knowing positive and negative sleep onset associations, having a consistent bedtime routine every night, maintaining consistent bedtime, considering a constant place for infant sleep, putting the infant in bed, awake but drowsy and using dream feed technic (table 1).

In the control group, we provided a 30-minute training session on general infant safety along with an educational pamphlet. During the eight weeks of follow-up, the researcher used weekly phone calls, text, and voice messages to communicate with the intervention group, while the control group received a phone call every other weak. To prevent the sample contaminations, we scheduled classes on different days for the two groups. Besides, mothers were asked not to share the information obtained with other mothers until the end of the study. Eight weeks after the educational intervention, the post-test infant sleep diary was again completed for four days and collected with other post-test questionnaires.

Outcome measurements

Demographic characteristics were designed with 13 questions on age, mothers' educational level, adequacy of the family monthly income, Childbirth method, Infant gestation age, gender, birth age and weight, birth order, breastfeeding status, room sharing, bed-sharing, and family support.

Infant sleep Diary

Mothers completed the diary for at least four days a week, once before the study and again eight weeks after training. Each page represented a full day and night divided into 10-minutes parts. Consequences were measured by this tool included “Nighttime Sleep” duration (22:00 to 8:00) (NTS), the “Longest Self-regulated Sleep period” (LSRS), Nighttime Awakenings with a Signal (NTAS), and bedtime. Given the common habit of infant late bedtime in Iran, it was impractical to shift it from midnight to 20:00 (routine bedtime in many studies). Therefore we considered bedtime as 22:00 and “Nighttime Sleep” as 22:00 to 08:00.

Pittsburgh Sleep Quality Index (PSQI)

Maternal sleep quality over the past month was measured by the 9-item PSQI questionnaire, including seven dimensions of subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, use of sleep pills, and daytime dysfunction. Each dimension’s score ranged from 0-3, and the global score was from 0-21—a total score \geq of 5 indicating low sleep quality. The scale’s sensitivity and specificity were 89.6% and 86.5%, respectively (Bysse, Reynolds III, & Monk, 1989).

Edinburgh Postnatal Depression Scale (EPDS)

The 10-item EPDS was applied to measure postnatal depression with a score range of 0-30. A score \geq of 13 denoted a higher likelihood of developing depression. The scale sensitivity and specificity were computed as 86% and 78%, respectively (Cox, Holden, & Sagovsky, 1987).

Usefulness of strategies

At the end of the study, we asked the mothers in the intervention group to describe each of the eight main strategies trained as “easy to apply,” “hard to apply,” “helpful,” or “unhelpful” technique.

Statistical Analysis

92 participants were required to create at least two scores clinically significant difference in maternal sleep quality in this study, with 80% power, 95% confidence interval, and assuming a 15% dropout rate. Chi-square, Fisher's exact test, and independent t-test were used to homogeneity the two groups. The results at baseline and after eight weeks within each group were compared with the Paired t-test, and outcomes for two intervention and control groups were evaluated through an Independent t-test. Results expressed as the mean (standard deviation). Confounding variables were controlled by ANCOVA. A significance level of P -value <0.05 was considered. All analysis was conducted by the statistical software SPSS 25.0.

Results

82 persons continued their participation until the end of the study. (Figure 1)

Baseline data

The average ages of mothers and infants were 29.6 years and 3.0 months, respectively. 73.1% of mothers had an academic degree. Statistics on delivery modes showed a significant difference between the two groups at the baseline. It didn't seem that this factor influences our results because our intervention started at least 70 days after delivery. 69.5% of infants were exclusively breastfed, with 97.5% and 14.6% of them had the experience of room-sharing and bed-sharing with parents, respectively (Table 2).

In the beginning, all infants had about an average of 3.79h "Longest Self-regulated Sleep" and 7.35h "Nighttime Sleep." Surprisingly, in our study, 94% of babies' bedtime at baseline was about 11 pm or later, and the range of it was between 10:30 pm and 4:00 am. In both groups, infants woke up about 2.75 times at night and called for their mothers.

Eight weeks after the training

The intervention group infants showed significant positive changes in "Longest Self-regulated Sleep," "Nighttime Sleep," and "Bedtime" ($P<0.001$). Without any significant difference, "Nighttime Awakenings with a Signal" was improved in both groups over time (Table 2).

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3 The mean “Longest Self-regulated Sleep” values were $4.3\text{h} \pm 1.1\text{ h}$ and $3.0 \pm 0.7\text{h}$ in the
4 intervention and control groups, respectively ($P < 0.001$). In the intervention group’s infants, the
5 mean “Nighttime Sleep” also increased significantly ($8.8 \pm 0.5\text{h}$) compared with the controls
6 ($7.5 \pm 0.8\text{h}$) ($P < 0.001$). Changing from 1:00 am to 22:20, the mean “bedtime” improved
7 significantly in the intervention group’s infants, while it altered from 00:52 am to 00:26 am in
8 the control group ($P < 0.001$).
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14 “Nighttime Awakenings with a Signal” numbers decreased slightly over time in both groups. In
15 the intervention group from 3.0 ± 2.2 time to 2.5 ± 0.9 and the control group from 2.9 ± 1.3 to
16 2.6 ± 1.1 . However, we didn’t find a significant difference between the two groups ($P = 0.64$)
17 (Table 3).
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22 Over time, the mean score of maternal sleep quality changed from 10.9 ± 2.9 to 8.9 ± 3.1 in the
23 intervention group, as well as 9.5 ± 3.5 to 9.6 ± 2.6 in the control group, indicating a significant
24 improvement in sleep quality of the mothers ($P > 0.05$). After the infant BSI, maternal depression
25 was also decreased significantly ($P > 0.05$), with a depression score falling from 10.9 to 8.9 in the
26 intervention group (Table 4).
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32 In the final survey on the trained methods, 88% of the intervention group mothers described
33 “maintaining a consistent bedtime for infants” as the most challenging technique, and about 66%
34 of them found “having a consistent bedtime routine” as the next hard strategy (table 5).
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38 Discussion

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41 In this study, “Nighttime Sleep,” “Longest Self-regulated Sleep,” and “Bedtime “were
42 significantly improved in the intervention group, while “Nighttime Awakenings with a Signal”
43 didn’t change significantly. After training, maternal sleep quality and depression were also
44 improved significantly in the intervention group.
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50 After eight weeks of follow up, both “Nighttime Sleep” and “Longest Self-regulated Sleep”
51 variables in the intervention group had an average of 1 hour and 21 minutes over the controls,
52 probably caused by enhanced mothers’ awareness of infant sleep signals, consistent bedtime, and
53 bedtime routine. Overall, this study’s baseline night sleep duration was 7 hours and 25 minutes,
54 equaling the minimum age-favored average (Hirshkowitz et al., 2015). A systematic review in
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3 2013 indicated the significant effect of BSI on the increased infant sleep duration (Bryanton,
4 Beck, & Montelpare, 2013). In Mindell's study, they experienced around 36 minutes more
5 "Nighttime Sleep" (Mindell, Telofski, Wiegand, & Kurtz, 2009). However, Stremler et al.
6 reported no significant changes in infant "Nighttime Sleep" at 6 and 12 weeks after BSI
7 intervention (Stremler et al., 2013), which could result from early postpartum training.
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12 Because the average infant bedtime in Iran is highly different from the expert recommendations
13 (19 to 20:00 (Iglowstein, Jenni, Molinari, & Largo, 2003)), Maintaining a proper, consistent
14 infants' bedtime was among our study's principal aims. In the present study, the baseline
15 bedtime in the intervention group was at 1:00 am, even far later than the mean bedtime in the
16 M.E. countries (22:45) (Mindell et al., 2017). After the intervention, bedtime improved
17 significantly by 2 hours and 40 minutes. It should be mentioned that consideration of the ideal
18 bedtime (19:00-20:00) could have discouraged our mothers due to the significant difference that
19 it had from their infants' actual bedtime. Therefore, concerning cultural sleep differences in Iran,
20 such as late-night family gatherings and parents' late bedtime, we considered 22:00 as the
21 acceptable infant bedtime. As other researchers suggest (Etherton et al., 2016; Jenni &
22 O'Connor, 2005), considering the cultural characteristics in BSI designing can play a key role in
23 maternal participation and the intervention's success. It is worth noting that a proper bedtime is a
24 typical standard in other cultures, so the bedtime variable was not measured in most studies or
25 didn't significantly change after the intervention (Mindell et al., 2018; Mindell et al., 2009).
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38 In our research, "Nighttime Awakenings with a Signal" didn't significantly change in the two
39 groups following BSI. This finding was also repeated in the systematic reviews in
40 2013 (Bryanton et al., 2013; Symon, Marley, Martin, & Norman, 2005) and 2016 (Kempner et al.,
41 2016). The most critical factor influencing "Nighttime Awakenings with a Signal" seems to be
42 the type of intervention, especially the extinction techniques (Mindell, Kuhn, Lewin, Meltzer, &
43 Sadeh, 2006)³⁴. However, we didn't use it because these techniques aren't recommended to
44 apply in infants younger than six months (Meltzer & Crabtree, 2015).
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51 This study significantly improved maternal sleep quality following the intervention ($P < 0.04$).
52 Improving infant sleep and implementing maternal sleep hygiene strategies led to better maternal
53 sleep quality, but maternal sleep quality remained low, given the PSQI's cut point. It should be
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3 considered that due to numerous young baby awakenings, these mothers' sleep alteration can be
4 completely normal.
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7 Similar results were also reported in the other studies (Hall et al., 2015; Mindell et al., 2011),
8 emphasizing the importance of health care providers and the mother's family support during this
9 period due to low sleep quality. Even some other studies reported no changes in maternal sleep
10 quality after BSI. This finding may be due to providing the intervention just after delivery
11 (Galland et al., 2017; Stremmer et al., 2013) or late face-to-face contact with parents (Harriet
12 Hiscock et al., 2014).
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19 In our study, the score of postnatal depression was significantly decreased in the intervention
20 group compared with the control group. The depression is likely to be influenced by improved
21 infant sleep. In two studies by Hiscock et al., the overall score of maternal depression was
22 significantly improved after infant BSI (Harriet Hiscock et al., 2007; Harriet Hiscock et al.,
23 2014). It seems that the 2-month follow-up interval in Hiscock studies and the present study was
24 enough time for stabilizing infant sleep routines and reducing maternal depression. In contrast, in
25 Stremmer (Stremmer et al., 2006) and Mindell (Mindell et al., 2018) studies, BSI interventions did
26 not show any effects on maternal depression. It might be due to early postnatal education or short
27 follow-up.
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36 As one of the few RCTs on infant BSI in M.E. countries, the present research provided mothers
37 individual, in-person training sessions instead of group sessions with some difficulties such as
38 being time-consuming. Selecting infants merely younger than six months was one of the study's
39 strengths. For the reason that there is a lack of well-controlled studies in this age group (Douglas
40 & Hill, 2013; Kempler et al., 2016; Martins et al., 2018) for claiming possible positive effects of
41 BSI on infants under six months. To omit the impact of attention, the control group also received
42 training about infant safety. Compared to similar studies, our study's weaknesses include small
43 sample size, costly lengthy interventions, and collection of infant sleep information from
44 mothers' reports through the sleep diary (we didn't utilize objective tools such as actigraph).
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52 For future studies, we recommend that more research take place in countries with different
53 cultures to have a better understanding of any society's sleep pattern other than
54 western/European countries. Maybe some of these habits would be negative and should be
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3 changed, but the community looks at them as a culture and don't believe those can or should be
4 changed. We can find the benefits or harms of our sleep and parenting cultures through more
5 researches in different societies. Our other suggestion is to try just one behavioral intervention in
6 each study to understand which intervention can make infants' sleep habits or affect them due to
7 the highest variability in infant sleep at the age of under six months old.
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12 13 **Conclusion**

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16 An increase of 1 hour and 20 minutes in infant "Nighttime Sleep," as well as the improved
17 earlier bedtime by 2 hours and 40 minutes, was evidence of the positive effect of early infant
18 BSI.
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22 Promotion of maternal mood and sleep quality in this study could be an answer to the doubt
23 mentioned by Dr. Mindell(Mindell et al., 2010) and Dr.Sadeh (Sadeh et al., 2010), likely
24 usefulness of infant BSI in Asian or M.E. countries, where adult late bedtime is the dominant
25 pattern.
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30 Despite the significant improvement of maternal sleep quality after the intervention, it still
31 remained low. Consistent with some other studies (Hall et al., 2015Mindell et al., 2011), these
32 results implied the necessity of attention to mothers during this period.
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37 It should be noted that finding the best infant BSI requires considering each society's cultural
38 characteristics, entailing research, and determining infant and parental sleep characteristics.
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41 **Conflicts of Interest**

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44 The authors declare no conflict of interest.
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50 **Acknowledgment**

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53 - This work was supported by the Tehran University of Medical Sciences (Grant No. 97-02-28-
54 38087) and Ethic committee reference number: I.R.TUMS.FNM.REC.1397.036.
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3 The research team is very grateful to Dr. Mehdi Yaseri and Dr. Maryam rad for consulting about
4 analysis, Dr. Elahe Amini for developing the content of interventions, and Dr. Jodi Mindell for
5 helpful suggestions.
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For Peer Review

References:

- Alamian, A., Wang, L., Hall, A. M., Pitts, M., & Ikekwere, J. (2016). Infant sleep problems and childhood overweight: Effects of three definitions of sleep problems. *Preventive Medicine Reports*, 4, 463-468. doi:<https://doi.org/10.1016/j.pmedr.2016.08.017>
- Bayer, J. K., Hiscock, H., Hampton, A., & Wake, M. (2007). Sleep problems in young infants and maternal mental and physical health. *Journal of Paediatrics and Child Health*, 43(1-2), 66-73. doi:<https://doi.org/10.1111/j.1440-1754.2007.01005.x>
- Bryanton, J., Beck, C. T., & Montelpare, W. (2013). Postnatal parental education for optimizing infant general health and parent-infant relationships. *Cochrane Database of Systematic Reviews*(11). doi:<https://doi.org/10.1002/14651858.CD004068.pub4>
- Byssse, D., Reynolds III, C., & Monk, T. (1989). The Pittsburgh Sleep Quality Index (PSQI): a new instrument for psychiatric research and practice. *Psychiatry Research*, 28(2), 193-213.
- Cox, J. L., Holden, J. M., & Sagovsky, R. (1987). Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. *The British Journal of Psychiatry*, 150(6), 782-786. doi:<https://psycnet.apa.org/doi/10.1192/bjp.150.6.782>
- Crichton, G. E., & Symon, B. (2016). Behavioral Management of Sleep Problems in Infants Under 6 Months--What Works? *Journal of Developmental and Behavioral Pediatrics*, 37(2), 164-171. doi:<https://doi.org/10.1097/dbp.0000000000000257>
- Douglas, P. S., & Hill, P. S. (2013). Behavioral Sleep Interventions in the First Six Months of Life Do not Improve Outcomes for Mothers or Infants: A Systematic Review. *Journal of Developmental & Behavioral Pediatrics*, 34(7), 497-507. doi:<https://doi.org/10.1097/DBP.0b013e31829cafa6>
- Etherton, H., Blunden, S., & Hauck, Y. (2016). Discussion of extinction-based behavioral sleep interventions for young children and reasons why parents may find them difficult. *Journal of clinical sleep medicine: JCSM: official publication of the American Academy of Sleep Medicine*, 12(11), 1535. doi:<https://doi.org/10.5664/jcsm.6284>
- Galland, B. C., Sayers, R. M., Cameron, S. L., Gray, A. R., Heath, A. L. M., Lawrence, J. A., . . . & Taylor, R. W. (2017). Anticipatory guidance to prevent infant sleep problems within a randomised controlled trial: infant, maternal and partner outcomes at 6 months of age. *BMJ Open*, 7(5), 11. doi:<http://dx.doi.org/10.1136/bmjopen-2016-014908>
- Hall, W. A., Hutton, E., Brant, R. F., Collet, J. P., Gregg, K., Saunders, R., ... & Bhagat, R. (2015). A randomized controlled trial of an intervention for infants' behavioral sleep problems. *BMC pediatrics*, 15(1), 181. doi:<https://doi.org/10.1186/s12887-015-0492-7>
- Hamshahri Media Research and Studies Center. (2008). Phone survey of the people of Tehran about sleep. Retrieved from <https://www.hamshahrionline.ir/news/63615>

1
2
3 Henderson, J. M., France, K. G., & Blampied, N. M. (2011). The consolidation of infants'
4 nocturnal sleep across the first year of life. *Sleep medicine reviews*, 15(4), 211-220.
5 doi:<https://doi.org/10.1016/j.smr.2010.08.003>
6

7
8 Hirshkowitz, M., Whiton, K., Albert, S. M., Alessi, C., Bruni, O., DonCarlos, L., . . .
9 Kheirandish-Gozal, L. (2015). National Sleep Foundation's sleep time duration
10 recommendations: methodology and results summary. *Sleep Health: Journal of the National*
11 *Sleep Foundation*, 1(1), 40-43. doi:<https://doi.org/10.1016/j.sleh.2014.12.010>
12

13 Hiscock, H., Bayer, J., Gold, L., Hampton, A., Ukoumunne, O. C., & Wake, M. (2007).
14 Improving infant sleep and maternal mental health: a cluster randomised trial. *Archives of*
15 *Disease in Childhood*, 92(11), 952-958. doi:<http://dx.doi.org/10.1136/adc.2006.099812>
16

17
18 Hiscock, H., Cook, F., Bayer, J., Le, H. N., Mensah, F., Cann, W., St James-Roberts, I. (2014).
19 Preventing early infant sleep and crying problems and postnatal depression: a randomized trial.
20 *Pediatrics*, 133(2), e346-e354. doi:<https://doi.org/10.1542/peds.2013-1886>
21

22 Hiscock, H., & Wake, M. (2001). Infant sleep problems and postnatal depression: a community-
23 based study. *Pediatrics*, 107(6), 1317-1322. doi:<https://doi.org/10.1542/peds.107.6.1317>
24

25 Hiscock, H., & Wake, M. (2002). Randomised controlled trial of behavioural infant sleep
26 intervention to improve infant sleep and maternal mood. *Brit Med J*, 324.
27 doi:[10.1136/bmj.324.7345.1062](https://doi.org/10.1136/bmj.324.7345.1062)
28

29
30 Iglowstein, I., Jenni, O. G., Molinari, L., & Largo, R. H. (2003). Sleep duration from infancy to
31 adolescence: reference values and generational trends. *Pediatrics*, 111.
32 doi:<https://doi.org/10.1542/peds.111.2.302>
33

34 Jenni, O. G., & O'Connor, B. B. (2005). Children's sleep: an interplay between culture and
35 biology. *Pediatrics*, 115(Supplement 1), 204-216. doi: <https://doi.org/10.1542/peds.2004-0815B>
36

37
38 Kempler, L., Sharpe, L., Miller, C. B., & Bartlett, D. J. (2016). Do psychosocial sleep
39 interventions improve infant sleep or maternal mood in the postnatal period? A systematic
40 review and meta-analysis of randomised controlled trials. *Sleep medicine reviews*, 29, 15-22.
41 doi:<https://doi.org/10.1016/j.smr.2015.08.002>
42

43 Martins, R. M., Oliveira, J. R., Salgado, C. C., Marques, B. L., Oliveira, L. C., Oliveira, G. R., . . .
44 . Ferreira, R. T. (2018). Sleep habits in infants: the role of maternal education. *Sleep Medicine*,
45 52, 138-144. doi:<https://doi.org/10.1016/j.sleep.2018.08.020>
46

47
48 Meltzer, L. J., & Crabtree, V. M. L. (2015). *Pediatric Sleep Problems: A Clinician's Guide to*
49 *Behavioral Interventions: American Psychological Association*.
50

51 Mindell, J. A., Du Mond, C. E., Sadeh, A., Telofski, L. S., Kulkarni, N., & Gunn, E. (2011).
52 Efficacy of an internet-based intervention for infant and toddler sleep disturbances. *Sleep*, 34(4),
53 451-458.B. doi:<https://doi.org/10.1093/sleep/34.4.451>
54
55
56
57
58
59
60

1
2
3 Mindell, J. A., Kuhn, B., Lewin, D. S., Meltzer, L. J., & Sadeh, A. (2006). Behavioral treatment
4 of bedtime problems and night wakings in infants and young children. *Sleep*, 29(10), 1263-1276.
5 doi:<https://doi.org/10.1093/sleep/29.10.1263>
6

7 Mindell, J. A., Lee, C., & Sadeh, A. (2017). Young child and maternal sleep in the Middle East.
8 *Sleep Medicine*, 32, 75-82. doi:<https://doi.org/10.1016/j.sleep.2016.11.011>
9

10 Mindell, J. A., Lee, C. I., Leichman, E. S., & Rotella, K. N. (2018). Massage-based bedtime
11 routine: impact on sleep and mood in infants and mothers. *Sleep Medicine*, 41, 51-57.
12 doi:<https://doi.org/10.1016/j.sleep.2017.09.010>
13
14

15 Mindell, J. A., Sadeh, A., Wiegand, B., How, T. H., & Goh, D. Y. (2010). Cross-cultural
16 differences in infant and toddler sleep. *Sleep Medicine*, 11(3), 274-280.
17 doi:<https://doi.org/10.1016/j.sleep.2009.04.012>
18

19 Mindell, J. A., Telofski, L. S., Wiegand, B., & Kurtz, E. S. (2009). A nightly bedtime routine:
20 impact on sleep in young children and maternal mood. *Sleep*, 32(5), 599-606.
21 doi:<https://doi.org/10.1093/sleep/32.5.599>
22
23

24 Nafeiy, Z., Shakiba, M., & Kashavarzian, F. (2009). The prevalence of sleep disorders in 1 to 2
25 year infants referring to Health Centers in Yazd, 2008-2009. *Toloo e Behdasht*, 8, 39-45.
26

27 Owais, S., Chow, C. H., Furtado, M., Frey, B. N., & Van Lieshout, R. J. (2018). Non-
28 pharmacological interventions for improving postpartum maternal sleep: A systematic review
29 and meta-analysis. *Sleep medicine reviews*, 41, 87-100.
30 doi:<https://doi.org/10.1016/j.smr.2018.01.005>
31
32

33 Raisi, F., Farnam, F., & Merghati-khoei, E. (2019). Understanding of the Iranian women of the
34 origin of their sexual dysfunctions: qualitative research. *Nursing and Midwifery Journal*, 17(1),
35 21-31(Persian). Retrieved from <http://unmf.umsu.ac.ir/article-1-3725-en.html>
36

37 Reuter, A., Silfverdal, S.-A., Lindblom, K., & Hjern, A. (2020). A systematic review of
38 prevention and treatment of infant behavioural sleep problems. *Acta Paediatrica*, 109(9), 1717-
39 1732. doi:<https://doi.org/10.1111/apa.15182>
40
41

42 Sadeh, A., Tikotzky, L., & Scher, A. (2010). Parenting and infant sleep. *Sleep medicine reviews*,
43 14(2), 89-96. doi:<https://doi.org/10.1016/j.smr.2009.05.003>
44

45 Schmid, G., Schreier, A., Meyer, R., & Wolke, D. (2010). A prospective study on the persistence
46 of infant crying, sleeping and feeding problems and preschool behaviour. *Acta Paediatrica*,
47 99(2), 286-290. doi:<https://doi.org/10.1111/j.1651-2227.2009.01572.x>
48

49 Smart, J., & Hiscock, H. (2007). Early infant crying and sleeping problems: a pilot study of
50 impact on parental well-being and parent-endorsed strategies for management. *Journal of*
51 *Paediatrics and Child Health*, 43(4), 283-290. doi:[https://doi.org/10.1111/j.1440-](https://doi.org/10.1111/j.1440-1754.2007.01060.x)
52 [1754.2007.01060.x](https://doi.org/10.1111/j.1440-1754.2007.01060.x)
53
54

55 Stremmler, R., Hodnett, E., Kenton, L., Lee, K., Weiss, S., Weston, J., & Willan, A. (2013). Effect
56 of behavioural-educational intervention on sleep for primiparous women and their infants in
57
58
59

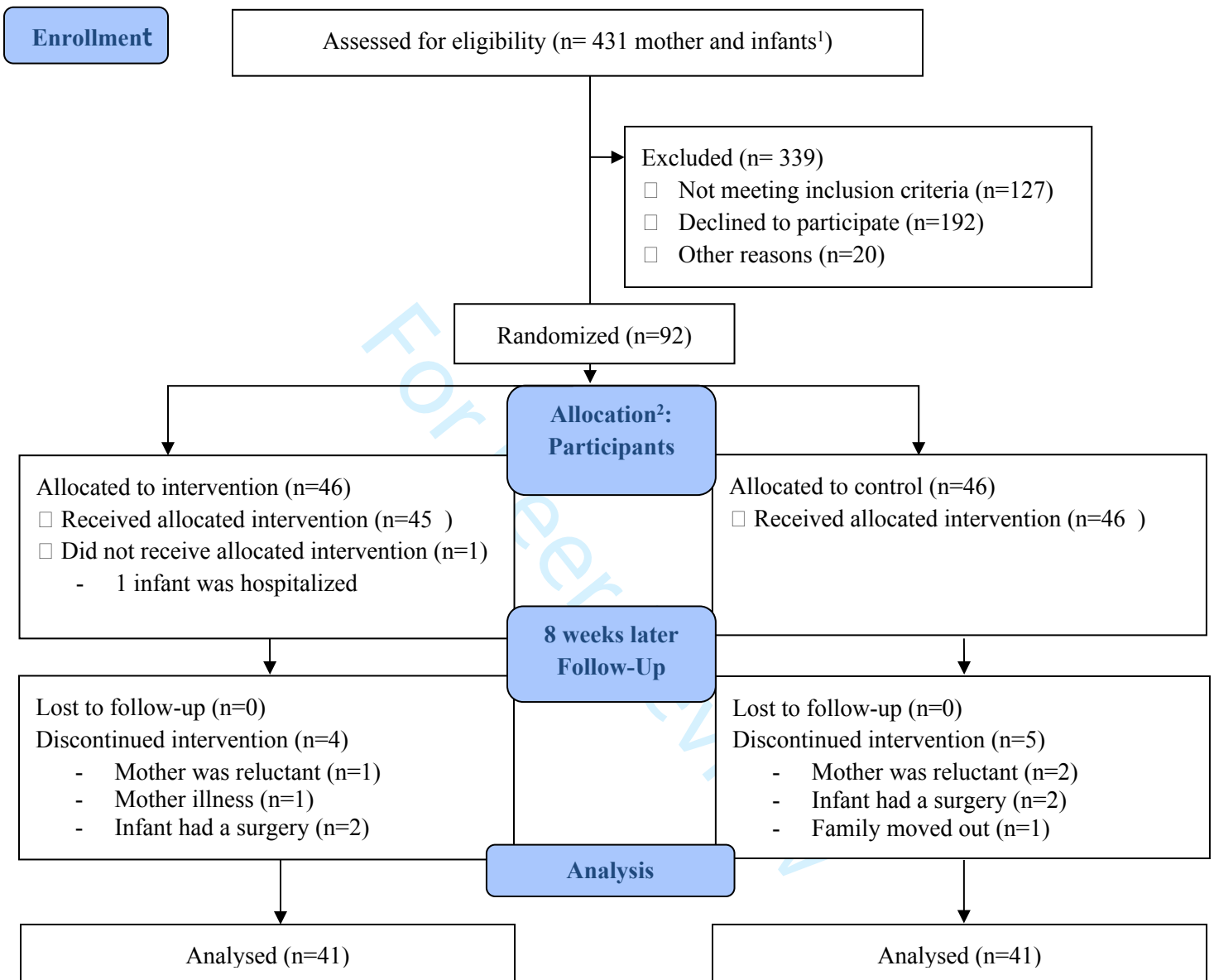
1
2
3 early postpartum: multisite randomized controlled trial. *BMJ*, 346, f1164.
4 doi:<https://dx.doi.org/10.1136%2Fbmj.f1164>
5

6
7 Stremler, R., Hodnett, E., Lee, K., MacMillan, S., Mill, C., Ongcangco, L., & Willan, A. (2006).
8 A behavioral-educational intervention to promote maternal and infant sleep: a pilot randomized,
9 controlled trial. *Sleep*, 29(12), 1609-1615. doi:<https://doi.org/10.1093/sleep/29.12.1609>
10

11
12 Symon, B. G., Marley, J. E., Martin, A. J., & Norman, E. R. (2005). Effect of a consultation
13 teaching behaviour modification on sleep performance in infants: a randomised controlled trial.
14 *The Medical Journal of Australia*, 182(5), 215-218. doi:[https://doi.org/10.5694/j.1326-](https://doi.org/10.5694/j.1326-5377.2005.tb06669.x)
15 [5377.2005.tb06669.x](https://doi.org/10.5694/j.1326-5377.2005.tb06669.x)

16
17 Tikotzky, L., De Marcas, G., Har-Toov, J., Dollberg, S., Bar-Haim, Y., & Sadeh, A. (2010).
18 Sleep and physical growth in infants during the first 6 months. *Journal of sleep research*,
19 19(1-Part-I), 103-110. doi:<https://doi.org/10.1111/j.1365-2869.2009.00772.x>
20

21
22 Touchette, É., Petit, D., Tremblay, R. E., & Montplaisir, J. Y. (2009). Risk factors and
23 consequences of early childhood dyssomnias: New perspectives. *Sleep medicine reviews*, 13(5),
24 355-361. doi:<http://dx.doi.org/10.1016/j.smr.2008.12.001>
25
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27
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1 Mother and infant considered as one participant

2 since we had just one care provider, “allocation: care providers “have been omitted

Figure 1. Flow diagram of study design

Table 1. Content presented in the class about infant sleep

The normal range of age-dependent sleep and awakenings
Benefits of adequate infant sleep
Perceiving an infant's weakness or sleepiness signals
Learning about positive and negative sleep onset associations
Knowing about night time feeding
Having a consistent bedtime routine every night
Considering a constant place for infant sleep
Making a difference between day and night for the baby
Using some behavioral strategies such as <ul style="list-style-type: none"> - focal feed (Dream feed) - putting the infant in bed, awake but drowsy - changing infant cycle to sleep-feed-play instead of feed-sleep-play - using white noises - using bedtime routines - avoiding digital instrument and T.V lights in the evening - using the daylight in the morning and lessening the light and noise of the house in the afternoon (making differences between day and night) - avoiding stimulating, talking, or adding the light for changing a diaper in the middle of the night
Knowing about Infant general and sleep safety
Knowing about Mother's sleep hygiene

Table 2. Baseline demographic variables for infants and parents

Categories	Intervention Group (n=41) M (SD)	Control Group (n=41) M (SD)	P-Value
Mothers age (year)	30.19 (4.6)	29.12 (2.2)	NS †
Infant age (months)	3.19 (0.8)	2.81 (0.8)	NS †
Infant gestation age (weeks)	38.60 (0.8)	38.78 (1.1)	NS †
Infant birth weight (KG)	3.48 (42.8.)	3.49 (32.4)	NS †
	N (%)	N (%)	
Childbirth method:			
- Vaginal delivery	12 (29.3)	24 (58.5)	0.008** ¥
- C-section	29 (70.7)	17 (41.5)	
Family support	32 (78)	36 (87.8)	NS ¥
Mothers education			
- Primary or high school degree	12 (29.3)	10 (24.4)	NS ¥
- Undergraduate	25 (61)	22 (53.7)	
- Postgraduate	4 (9.8)	9 (22.0)	
Family economic status			
- Inappropriate	2 (4.9)	1 (2.4)	NS †
- Middle range	26 (63.4)	30 (73.2)	
- Appropriate	13 (31.7)	10 (24.4)	
Infant birth order:			
- First child	22 (53.7)	21 (51.2)	NS ¥
- Second child	19 (46.3)	20 (48.8)	
Infant gender:			
- Girl	18 (43.9)	19 (46.3)	N.S. ¥
Infant feeding:			
- Exclusive breastfeeding	24 (58.5)	33 (80.5)	NS †
- Mostly breastfeeding	12 (29.3)	5 (12.2)	
- Only formula	1 (2.4)	2 (4.9)	
- Mostly formula	4 (9.8)	1 (2.4)	
Bed-sharing with parents			
- Yes	8 (19.5)	4 (9.8)	N.S. ¥
- No	33 (80.5)	37 (90.2)	
Room sharing with parents			
- Yes	39 (95.1)	41 (100)	N.S. †
- No	2 (4.9)	0	

NS: Non-significant. † Analyzed by the Independent t-test, ‡ Analyzed by the Fisher's exact test, ¥ Analyzed by the Pearson chi-square, p<0.01 **

Table 3. Infant sleep characteristics at baseline and 8 weeks later

		Intervention Group n=41	Control Group n=41	p-value	95% confidence interval
		Mean(S.D.)			
Nighttime sleep duration (NTS). Hour	Baseline	7.41 (1.05)	7.24 (0.95)	0.434 †	-0.26, 0.61
	8 weeks	8.89 (0.57)	7.53 (0.82)	<0.001*** €	1.03, 1.66
Longest self-regulated sleep (LSRS). Hour	Baseline	3.24 (0.86)	2.97 (0.75)	0.132 †	-0.08, 0.62
	8 weeks	4.35 (1.12)	3.00 (0.74)	<0.001*** €	0.93, 1.77
Nighttime awakenings with signals (NTAS). Number	Baseline	3.0 (2.22)	2.9 (1.33)	0.729 †	-0.66, 0.94
	8 weeks	2.5 (0.95)	2.6 (1.18)	0.645 €	-0.55, 0.39
Bedtime	Baseline	01:00 a.m. (1h, 44min)	00:52 a.m. (1h, 23min)	0.622 †	23:29, 0:51
	8 weeks	22:20 (1h, 7min)	00:25 a.m. (56min)	<0.001*** €	21:29,22:16

† Analyzed by the Independent t-test, ‡ Analyzed by the paired t-test, € Analysis of covariance (ANCOVA),
P<0.001***

Table 4. Mothers sleep quality and depression at baseline and 8 weeks later

		Intervention Group (n=41)	Control group (n=41)	p-value	95% confidence interval
		Mean(S.D.)			
PSQI global score ¹	Baseline	10.90 (2.96)	9.54 (3.54)	0.062†	-0.06,2.80
	8 weeks	8.95 (3.16)	9.68 (2.67)	0.040* €	-2.01,0.55
EPDS score ²	Baseline	9.02 (4.65)	9.46 (5.16)	0.687†	-2.59,1.72
	8 weeks	7.22 (4.29)	9.07 (6.10)	0.045* €	-4.17,0.46

¹ Pittsburgh Sleep Quality Index, ² Edinburgh Postnatal Depression Scale, † Analyzed by the Independent t-test, ‡ Analyzed by the paired t-test, € Analysis of covariance (ANCOVA), P<0.05*

Table 5. Helpfulness and hardness of intervention strategies

Presented strategy	Easy to apply n (%)	Hard to apply n (%)	Helpful n (%)	Unhelpful n (%)
Making differences between day and night	34 (82.9)	7 (17)	41 (100)	0
Assigning a constant place for infant sleep	34 (82.9)	7 (17)	33 (80.5)	8 (19.5)
Maintaining consistent “bedtime” for infant sleep	5 (12.2)	36 (87.8)	30 (73.2)	11 (26.8)
Having a consistent bedtime routine	14 (34.1)	27 (65.9)	32 (78.0)	9 (22.2)
Putting infant in bed, awake but drowsy	17 (41.5)	24 (58.5)	31 (75.6)	10 (24.2)
Using the Focal feed	26 (63.4)	15 (36.6)	34 (82.9)	7 (17.1)
Applying infant’s safe sleep strategies	32 (78.0)	9 (22.0)	37 (90.2)	4 (9.8)
Mother's sleep hygiene, and nutrition	26 (63.4)	15 (36.6)	41 (100)	0