

Implementation and Effects of an Online Intervention Designed to Promote Sleep During Early Infancy: A Randomized Trial

Stephanie Anzman-Frasca^{1,2}, Juliana Goldsmith¹, Amanda B Hassinger^{1,3}, Jennifer S Savage⁴, Vaishali Gupta¹

¹Department of Pediatrics, Jacobs School of Medicine and Biomedical Sciences, Division of Behavioral Medicine, University at Buffalo, Buffalo, NY, USA; ²Center for Ingestive Behavior Research, University at Buffalo, Buffalo, NY, USA; ³Department of Pediatrics, University at Buffalo Jacobs School of Medicine and Biomedical Sciences, Division of Pulmonology and Sleep Medicine, John R. Oishei Children's Hospital, Buffalo, NY, USA; ⁴Center for Childhood Obesity Research, Department of Nutritional Sciences, The Pennsylvania State University, University Park, PA, USA

Correspondence: Stephanie Anzman-Frasca, G56 Farber Hall University at Buffalo South Campus, Buffalo, NY, 14214, USA, Tel +1-716-829-6692, Email safasca@buffalo.edu

Objective: Examine the implementation and effects of an interactive online intervention designed to support new parents with their young infants' sleep.

Design: First-time parents were enrolled when infants were ~6 weeks old and randomized to a sleep intervention or general baby care control group, with intervention content provided weekly between infant ages 2 to 4 months, primarily as brief videos and infographics in private online groups.

Methods: Parents (n=74) completed online surveys at baseline (infant age ~6 weeks), midpoint (3 months), post-intervention (4 months), and follow-up (7 months), reporting on infant sleep duration and night wakings (via Brief Infant Sleep Questionnaire), as well as their own sleep duration (via Pittsburgh Sleep Quality Index), and parenting satisfaction and self-efficacy (via Perceived Sense of Competence Scale). Marginal models examined sleep intervention effects on infants' total and nightly sleep duration and night wakings, parent sleep duration, and parenting satisfaction and self-efficacy over time.

Results: Eighty-one percent of parents joined the online groups. There was a group-by-time interaction predicting total infant sleep duration, with total sleep increasing in the intervention group relative to controls. Tests of least squares means showed that intervention group infants slept 1.4 hours longer than controls at age 4 months (p=0.004). There were no significant effects on infants' nighttime sleep, but daytime napping increased in the intervention group relative to controls (p=0.04). Group differences in parent sleep were not statistically significant but were in a consistent direction when compared with intervention impacts on infant sleep. Parenting satisfaction increased significantly in both groups.

Conclusion: Findings demonstrate the potential of an interactive online sleep intervention to support first-time parents with early infant sleep. Parent perspectives support acceptability of the approach and highlight the potential for further development of this scalable online intervention and examination of its impacts on additional aspects of well-being.

Clinical Trial Registration: The study was registered prior to participant enrollment at [clinicaltrials.gov](https://clinicaltrials.gov/study/NCT05322174) (NCT05322174). URL: <https://clinicaltrials.gov/study/NCT05322174>.

Keywords: sleep, infancy, online, intervention

Introduction

More than 20% of American infants and toddlers have sleep problems¹ such as problems falling asleep, staying asleep, or waking up refreshed. When a baby is not sleeping well, it can be stressful for parents, especially new parents who often then seek out help to improve infant sleep.^{2,3} Infant sleep evolves with development. During the newborn period, the circadian rhythm is not established, so there is an irregular sleep schedule with frequent short periods of sleep. Sleep cycles are short with predominantly REM sleep to allow for rapid neurologic development. The circadian rhythm becomes evident around 2 to 3 months of age⁴ with ongoing development of the long overnight sleep period across the months that follow. Infants start to develop the ability to self-soothe at sleep onset with variability in when and to what

extent more independent and consolidated sleep occurs. Early infant sleep interventions may support independent sleep development over time and impact other aspects of infant and family well-being.

While many infant sleep interventions begin after age 6 months, there is evidence supporting the potential to help new parents with infant sleep prior to this time point, offering the opportunity to gradually set the stage for healthy sleep and the positive outcomes that could stem from it in a developmentally appropriate manner. For example, INSIGHT, a randomized controlled trial, used nurse home visits to promote responsive parenting in several behavioral domains, including sleep. Intervention content designed to help new parents understand and support their infant's sleep was delivered within the first month after birth, with group differences in sleep first emerging at age 8 weeks.⁵ Correspondingly, a review by Crichton and Symon⁶ showed that it is possible to impact infant sleep before age 6 months, with particular support for studies that focused on supporting infants' developing abilities to self-settle. In addition to infants' self-settling, sleep intervention content across the reviewed studies included educational information about normal infant sleep and sleep physiology, offering a feeding before bed, differentiating night from day, sleep cues, relaxation techniques, and implementing consistent routines. In a more recent review, which included but was not specifically focused on younger infants, sleep intervention topics were similar and included supporting self-settling, discussion of normal infant sleep and safe sleep, sleep location, and routines.⁷ This latter review showed that psychosocial infant sleep interventions improved infants' nocturnal sleep time and maternal depression.

Interventions delivered by clinicians have been shown to improve infant sleep⁴ but are resource intensive. Most early infant sleep interventions have been implemented in the clinic or via home visits.⁶ Online platforms provide an alternative model for intervention delivery and may reduce barriers that disproportionately impact families living with low incomes. In a 3-week, web-based intervention providing parents of 6 to 36 month olds with behavioral strategies to improve sleep, Mindell et al reported improvements in child sleep, including latency to sleep, night wakings, and nighttime sleep continuity, as well as maternal sleep and mood, with some evidence that improvements persisted.^{8,9} Despite these promising results, there is a dearth of research using online methods to support new parents with infant sleep early in infancy, highlighting an opportunity to develop and test remotely delivered, scalable interventions that provide parents with anticipatory guidance and developmentally-appropriate support for young infants' sleep.

The first 6 months can be a particularly challenging time for new parents, and pilot research has highlighted how online groups aiming to provide social support to new parents can be as effective as home-based support, though this research was not explicitly focused on sleep, with outcome measures including parenting competence and infant socioemotional development.¹⁰ The objective of the present study was to build upon the extant research on infant sleep during early infancy, specifically by examining the implementation of an interactive online intervention designed to provide first-time parents with developmentally-appropriate support for their infants' sleep from age 2 to 4 months. We tested the intervention's effects on infant total and nighttime sleep duration and number of night wakings, as well as parent sleep duration, parenting self-efficacy, and parenting satisfaction.

Methods

Participants

First-time, English-speaking US parents or legal guardians ≥ 18 years old (here forward referred to as parents) were recruited when their infant was ≤ 6 weeks old. Enrollment was timed such that infants would be about 6 weeks post-gestational age (6 ± 2 weeks) at enrollment and about 2 months of age at the start of study interventions. Exclusion criteria included lack of access to or interest in using a private group on social media providing support around infant sleep or baby care, parents of infants who are born premature (prior to 37 weeks gestational age), and parents of multiples (twins, triplets, etc). Of 797 potential participants completing the eligibility screener, 11.3% met inclusion criteria. The most common reasons for exclusion were infant age (ie the infant would not be ~ 2 months of age when the next round of intervention groups would begin, based on the reported due date or date of birth; 95%) or not being a first-time parent (ie, the infant about whom they filled out the eligibility survey was not their first child; 4%). Those eligible were invited to enroll using an online form, which described the study, and after participants indicated their agreement to participate via this form, they moved on to the online baseline survey. After completing the baseline survey, participants were randomized as described below. Enrollment continued until the number of randomized participants



corresponded to sample size goals ($n=74$ randomized). The CONSORT diagram showing screening, enrollment, and retention details is in [Supplemental Figure 1](#). Data collection occurred across two cohorts between April 2022 and February 2023.

Infants were 54% male, 50% non-Hispanic white, 32% Black, and 16% Hispanic/Latino ([Table 1](#)). Study procedures were approved by the University at Buffalo Institutional Review Board, and all participants completed informed consent before enrollment. The study was registered prior to enrollment at [clinicaltrials.gov](#) (NCT05322174). All study activities were remote, with intervention content provided via online groups; contact with study staff occurring via email, videoconference, and/or phone; and participants completing 4 online surveys between enrollment and 7-month follow-up, with study payments after each survey.

Procedures

Interventions

Participants were randomly assigned to a sleep intervention or general baby care control group, in which aspects of baby care besides sleep would be reviewed ([Supplemental Table 1](#)). The trial design was parallel with block size 2 and a 1:1 allocation ratio. Randomization was stratified by infant feeding mode reported at enrollment: breastfeeding, formula feeding, or mixed feeding. The randomization sequence was generated by a statistician who was not otherwise involved with the study, and the study staff who interacted with participants did not review the spreadsheet containing this information until it was time to randomize participants. Study overview packets and baby care items were mailed to all participants after randomization, with the intervention group receiving two sleep sacks, information on white noise applications to download, and a commercially-available e-book about infant sleep.¹¹ The control group received items of a similar value related to general baby care: hooded towels and wash cloths, nail clippers, and the e-book *Your Baby's*

Table 1 Demographic Characteristics of Study Participants at Baseline

	Mean \pm SD or Frequency (%)		
	All (n=74)	Sleep Intervention (n=36)	Control (n=38)
Infants			
Gender	54.1% male, 46.0% female	50.0% male, 50.0% female	57.9% male, 42.1% female
Age	6.2 \pm 1.3 weeks	6.1 \pm 1.2 weeks	6.3 \pm 1.4 weeks
Ethnicity	16.2% Hispanic/Latino	19.4% Hispanic/Latino	13.2% Hispanic/Latino
Race ^a	62.2% white, 32.4% Black, 5.4% American Indian/Alaskan Native, 5.4% Asian, 6.8% multiracial, 1.4% other race	66.7% white, 27.8% Black, 2.8% American Indian/Alaskan Native, 5.6% Asian, 5.6% multiracial, 0.0% other race	57.9% white, 36.8% Black, 7.9% American Indian/Alaskan Native, 5.3% Asian, 7.9% multiracial, 2.6% other race
Parents			
Age ^b	31.0 \pm 5.0 years	31.2 \pm 4.9 years	30.7 \pm 5.1 years
Ethnicity	9.5% Hispanic/Latino	11.1% Hispanic/Latino	7.9% Hispanic/Latino
Race	60.8% white, 31.1% Black, 2.7% American Indian/Alaskan Native, 5.4% Asian, 1.4% multiracial, 2.7% prefer not to answer	63.9% white, 27.8% Black, 0.0% American Indian/Alaskan Native, 5.6% Asian, 2.8% multiracial, 2.8% prefer not to answer	57.9% white, 34.2% Black, 5.3% American Indian/Alaskan Native, 5.3% Asian, 0% multiracial, 2.6% prefer not to answer
Relation to child	97.3% mother; 2.7% father (100% identified as a primary caregiver)	100% mother	94.7% mother, 5.3% father
Education	2.7% high school, 2.7% some college, 4.1% Associate's degree, 48.7% Bachelor's degree, 41.9% graduate or professional degree	2.8% high school, 0.0% some college, 5.6% Associate's degree, 41.7% Bachelor's degree, 50.0% graduate or professional degree	2.6% high school, 5.3% some college, 2.6% Associate's degree, 55.3% Bachelor's degree, 34.2% graduate degree
Marital status	86.5% married, 8.1% living with partner, 5.4% never married	91.7% married, 2.8% living with partner, 5.6% never married	81.6% married, 13.2% living with partner, 5.3% never married
Annual household income	4.1% \$15K-\$24,999/yr	2.8% \$15K-\$24,999/yr	5.3% \$15K-\$24,999/yr
	4.1% \$25K-\$34,999	2.8% \$25K-\$34,999	5.3% \$25K-\$34,999
	4.1% \$35K-\$49,999	2.8% \$35K-\$49,999	5.3% \$35K-\$49,999
	17.6% \$50K-\$74,999	13.9% \$50K-\$74,999	21.1% \$50K-\$74,999
	23.0% \$75K-\$99,999	19.4% \$75K-\$99,999	26.3% \$75K-\$99,999
	32.4% \$100K-\$149,999	38.9% \$100K-\$149,999	26.3% \$100K-\$149,999
	9.5% \$150K or more	16.7% \$150K or more	2.6% \$150K or more
	5.4% prefer not to answer	2.8% prefer not to answer	7.9% prefer not to answer

Notes: Demographics above did not differ significantly by study group. In cases where percentages do not total 100, this is typically due to rounding. ^aAn exception is the race data, for which participants were able to select all categories with which they identified, and the percentage of the 74 participants who indicated each category is shown.

^bn=71 (3 preferred not to answer).

First Year.¹² Participants were also invited to a private, study-specific online group within an existing social media platform.

Intervention content was shared weekly in the form of original videos (~5-7 minutes) and infographics in the online group. Content corresponded to the provided e-book and was dose matched between groups. The principal investigator (SAF) created the outline of topics covered in each group ([Supplemental Table 1](#)); content was evidence-based, developmentally appropriate, and consistent with recommendations from the American Academy of Pediatrics. For example, in the sleep intervention group, the first week of content, delivered around infant age 2 months, included information on creating a safe sleep space and the use of developmentally-appropriate tools that could help with infant sleep, such as swaddling (prior to infants learning to roll over onto their stomachs) and white noise no louder than 55 decibels. Parents were also advised to start observing when their child sleeps but were not yet given any information on trying to change this at this early stage. In Week 2, parents were given more information about “how sleep works”, including how to identify the emergence of the circadian rhythm and guidance on setting up an initial bedtime routine. Later in the intervention, content included starting to establish a consistent time for nighttime sleep onset, structuring naps (pre-nap routine, timing), and nighttime parenting techniques that support the development of self-settling in a gradual manner that is responsive to the infant’s cues, needs, and development. Participants could post questions and interact in the groups, and group moderators provided support that was consistent with the intervention curriculum.

Weekly posts in the online groups occurred from infant ages 2 to 4 months. Participants continued to have access to their group until age 7 months. Of those enrolled in the study, 81% joined their private online group (control group n=28; intervention n=32). Participants who did not join the online group were sent weekly reminders to join, with that week’s study infographic attached. Even though these participants did not experience interaction in the groups, they still were provided with access to intervention content via the infographics and e-book.

Measures

Unless otherwise specified, each of the following survey measures was administered at baseline (6 weeks of age), intervention midpoint (3 months), post-intervention (4 months), and follow-up (7 months).

Sleep Outcomes

Infant Sleep

Questions from the short form of the Brief Infant Sleep Questionnaire¹³ were used to collect parent-reported infant sleep over the past 7 days, including typical sleep duration and number of night wakings. Total sleep duration was calculated as the sum of reported nighttime (7pm-7am) and daytime (7am-7pm) sleep. This questionnaire has been validated against actigraphy, an objective sleep measure.

Parent Sleep

Parent nighttime sleep duration was measured using the Pittsburgh Sleep Quality Index.¹⁴ The primary operationalization of this variable followed Pittsburgh Sleep Quality Index scoring guidelines, turning continuous nighttime sleep duration into a 4-point ordinal variable representing lower vs higher amounts of sleep. We also provide continuous parent sleep duration values descriptively for interpretability.

Parenting Outcomes

The Perceived Sense of Competence Scale was used to assess parenting self-efficacy and parenting satisfaction.¹⁵ Items were rated on a 6-point scale from strongly disagree (1) to strongly agree (6).

Demographics

At baseline, parents reported their infant’s date of birth and race/ethnicity and their own age, race/ethnicity, marital status, education, and annual household income.

Intervention Implementation and Acceptability

Intervention engagement was defined as whether parents joined their online group. Intervention implementation was tracked using data available in the online groups (eg, number of unique views of videos and infographics). Questions about experiences with intervention materials (eg, use of baby items sent in the welcome packet; use and feelings about the online group and e-book) were used to assess intervention acceptability.

Data Analysis

Sample Size Calculation

The sample size was estimated using $\alpha=0.05$, power=0.80, and Cohen's $d=0.80$, which is supported by Mindell et al's online intervention.⁸ This calculation yielded an estimated sample size of 52, which was increased by about 20% to be conservative (eg, given the potential for attrition).

Analysis

To describe the sample's characteristics, we examined descriptive statistics and distributions for variables of interest, Pearson correlations between key variables at baseline, and whether study groups differed on baseline demographics, baseline infant feeding mode, or intervention engagement. We summarized information from intervention implementation and acceptability measures, including summarizing engagement with content posted in the online groups among the participants who joined the groups.

Marginal models in SAS Proc Mixed examined the overall study group effect and the group-by-time interaction predicting infant total and nightly sleep duration, number of infant night wakings, parent sleep duration, and parenting satisfaction and self-efficacy. We compared and selected the best-fitting error structure for each model and examined model assumptions using diagnostic plots. We included all randomized participants in these models and adjusted for the following as fixed effects: status on the outcome of interest at baseline, infant feeding mode (ie the stratification variable), and study cohort (1 or 2). In these models, time (occasions within subject) was the only random effect. Model results were consistent with those reported herein when examining study cohort as a random effect. In addition to these models, we examined supporting models with additional covariates included. Results were consistent with those reported herein when adjusting for infant sex, intervention engagement, infant age, and primary caregiver status. We also explored intervention effects on infant daytime sleep as a post-hoc analysis, given the nature of the findings for total and nighttime sleep. We compared least squares means between groups at each time point to shed light on the nature of observed effects by requesting least squares means output for the group-by-time interaction in the context of the marginal models. We expected all infants' sleep to change with developmental time; key questions were whether this intervention impacted those changes and whether effects extended beyond infant sleep to parent variables. The pre-specified alpha level was 0.05.

Results

Descriptive Statistics and Initial Study Group Differences

There were no statistically significant study group differences in demographics, infant feeding mode, or intervention engagement. Descriptive statistics for variables of interest at baseline and inter-correlations between them are in [Table 2](#).

Intervention Implementation and Acceptability

On average, 74.2% of intervention-group participants and 79.5% of control-group participants who joined their online group viewed posted videos. There was an average of 1.8 comments per weekly video post in the intervention group and 1.2 in the control group. On average, 70.6% of intervention-group participants and 79.5% of control-group participants who joined their online group viewed the posted infographics.

At intervention midpoint, substantial percentages of sleep intervention group participants reported that the intervention components were useful, with 67.7% of the overall study sample finding the provided baby products very useful (26.5% sort of useful; 5.9% not useful), 50.0% finding the provided e-book very useful (47.1% sort of useful, 2.9% not useful), and 52.9% finding the online group very useful (44.1% sort of useful, 2.9% not useful). Responses were similar

Table 2 Descriptive Statistics and Inter-Correlations Between Variables of Interest Measured at Baseline (n=74)

	Mean (SD)	Correlations: 1. Infant Total Sleep	2. Infant Night Sleep	3. Infant Night Wakings	4. Parent Night Sleep	5. Parenting Satisfaction
1. Infant total sleep duration (hours in 24-hour period)	14.6 (2.8)	–				
2. Infant nighttime sleep duration (hours from 7pm-7am)	8.3 (1.7)	0.61****	–			
3. Infant number of night wakings	2.5 (1.2)	0.21 [#]	–0.02	–		
4. Parent nighttime sleep duration (hours) ^a	6.1 (1.6)	0.09	0.28*	0.06	–	
5. Parenting satisfaction	37.9 (7.3)	0.04	–0.03	0.07	0.05	–
6. Parenting self-efficacy	29.8 (6.2)	0.09	0.06	0.07	0.05	0.32**

Notes: ^aHere we show actual reported hours of nighttime sleep for interpretability. Significant correlations are bolded; [#]p<0.10 *p<0.05, **p<0.01, ****p<0.0001. Table depicts Pearson correlations.

in the control group, with 64.9% finding the baby products very useful and 64.9% and 54.1% rating the e-book and online group as very useful, respectively. Compared to the control group's experience, there was one extra step needed to access the intervention group's e-book, based on the format in which the book was available, and some participants expressed confusion related to this. Participants' impressions of the intervention content were similar from midpoint to post-intervention. After the intervention's conclusion, the majority of intervention-group participants (58.8%) reported that they had viewed content in their online group once per week or more, and 26.5% reported posting in the group. In the control group, 44.7% reported viewing content in the group once per week or more, and 15.8% reported posting in the groups.

Open-ended comments from participants shed more light on intervention acceptability. The majority of comments about the provided baby products were positive, with many parents from each group noting that the items were useful. Some parents noted that they already had similar products, and others noted issues with sizing such as the intervention group sleep sack not fitting properly or control group nail clippers being too big for the baby's nails. While many participants commented that the information in the e-book was useful, some noted that they had difficulty finding time to read it. In addition, some participants wished that they had a physical, versus electronic, copy of the book.

When asking participants about the private online groups, many found the posted information to be helpful. Some positive comments about the groups included that helpful information was presented both as a video and pdf, moderators were available to answer questions, and members did not feel alone in their new parenting journey, with many noting how it was helpful to hear about other parents' experiences. However, participants did wish there was more discussion and engagement from the other parents in the group (see Table 3).

Intervention Effects on Sleep

Infant Sleep

There was a significant group-by-time interaction predicting reported total infant sleep duration ($F=3.14$; $p=0.03$), representing a significant difference in how sleep duration changed over time by group. Changes in the least squares means over time are depicted visually in Figure 1 and show that the sleep intervention group had a slower decrease in total sleep duration across the study time points. A statistically significant group difference emerged at the end of the intervention at infant age 4 months: Control $M=13.39 \pm 2.13$ hours; Intervention $M=14.81 \pm 2.13$ hours; $p=0.004$. These differences were attenuated by follow-up at infant age 7 months (Control $M=12.78 \pm 2.13$ hours; Intervention $M=13.14 \pm 2.10$ hours;

Table 3 Intervention Implementation and Acceptability Results Among Parents Who Joined Their Online Group (n=32 Sleep Intervention, n=28 Control)

Week		1	2	3	4	5	6	7	8
Group									
Control	Viewed Video	93%	80%	80%	80%	87%	63%	73%	67%
	Viewed Infographic	83%	77%	73%	70%	77%	70%	67%	63%
	Viewed Video	100%	88%	76%	68%	68%	72%	68%	64%
	Viewed Infographic	88%	92%	76%	76%	68%	76%	64%	60%
Sample quotes from parents		"It's good to know what other parents are going through. Being a new parent is very isolating." "I liked reading what problems other parents had and what solutions were offered" "I wish more people had posted in the group" "Materials were helpful but figuring out a way to have the group more connected would have been nice" "The sleep sack was the largest help in getting him to sleep. It was a game changer. It kept the swaddle better than any other swaddle"							

p=0.47). There were no significant intervention effects on infant nighttime sleep duration or night wakings, but there was a similar significant group-by-time interaction predicting daytime sleep duration ($F=2.88$; $p=0.04$), with group differences again significant at the end of the intervention at infant age 4 months: Control $M=4.26 \pm 1.83$ hours; Intervention $M=5.21 \pm 1.83$ hours; $p=0.03$. Full results of these models, including all least squares means, can be found in Table 4.

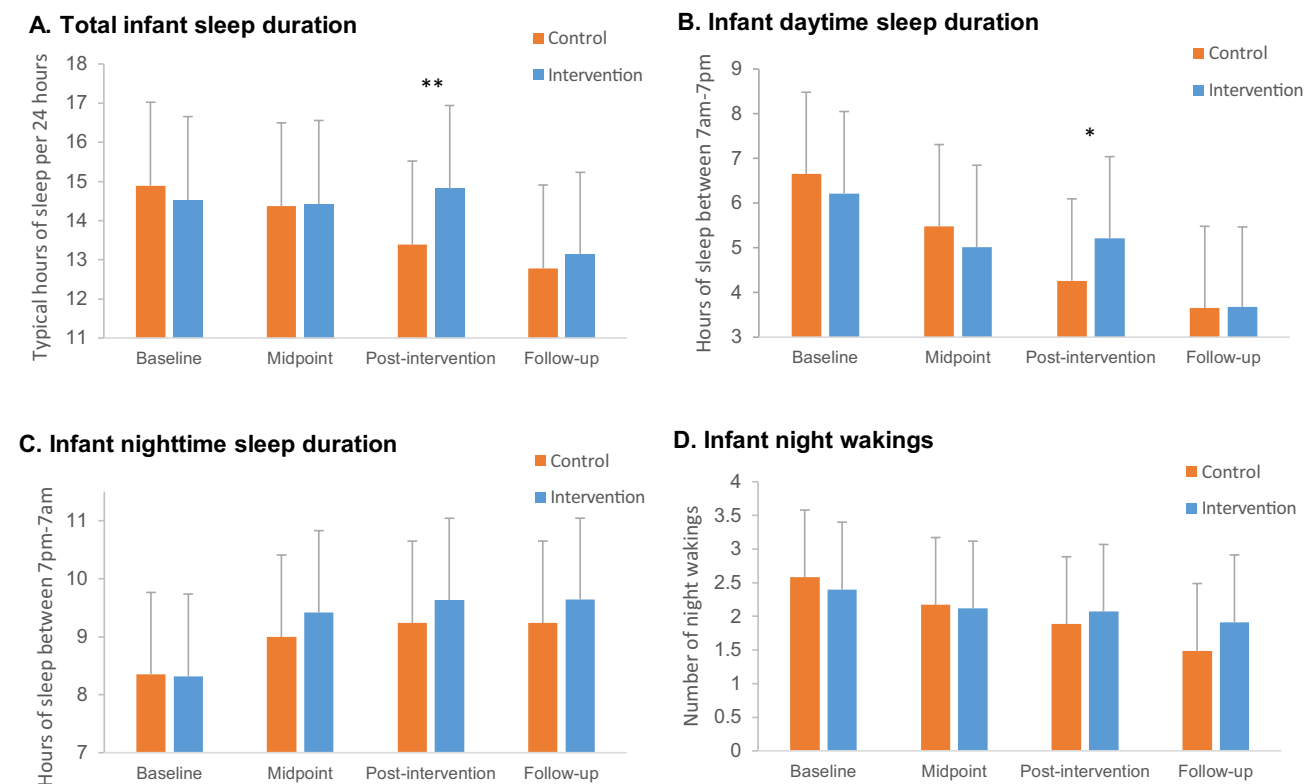


Figure 1 Sleep intervention effects on primary infant sleep outcomes from baseline (infant age ~6 weeks) through intervention midpoint (~3 months), post-intervention (~4 months), and follow-up (~7 months). There were significant group-by-time interactions predicting total (A) and daytime (B) infant sleep, such that total and daytime infant sleep duration were significantly different between the groups over time. Differences in nighttime sleep (C) and night wakings (D) were not statistically significant. Sample sizes at each time point are as follows: baseline: n=36 intervention, 38 control; midpoint: n=35 intervention, 38 control; post-intervention: n=34 intervention, 37 control; follow-up: n=34 intervention; 38 control. Marginal models utilized all available data via full information maximum likelihood (ie, all 74 participants are included in the analyses). Asterisks indicate whether comparisons of least squares means at individual time points were statistically significant between groups: * $p<0.05$; ** $p<0.01$.

Table 4 Model Results and Means by Study Group for Sleep and Parenting Outcomes (n=36 Sleep Intervention, n=38 Control Group in Models)

	F-value	p-value	Control Group LS Means (SE)	Sleep Intervention Group LS Means (SE)
<i>Infants' total sleep duration</i>				
Study group	1.92	0.17	Baseline: 14.89 (0.35)	Baseline: 14.52 (0.36)
Time	7.09	0.0001	Midpoint: 14.37 (0.35)	Midpoint: 14.42 (0.36)
Group-by-time interaction	3.14	0.03	Post: 13.39 (0.35)**	Post: 14.81 (0.37)**
Feeding mode	0.93	0.40	Follow-up: 12.78 (0.35)	Follow-up: 13.14 (0.37)
Cohort	6.00	0.02		
Baseline sleep	196.87	<0.0001		
<i>Infants' nighttime sleep duration</i>				
Study group	1.89	0.17	Baseline: 8.35 (0.23)	Baseline: 8.31 (0.24)
Time	12.97	<0.0001	Midpoint: 8.99 (0.23)	Midpoint: 9.42 (0.24)
Group-by-time interaction	0.73	0.53	Post: 9.23 (0.23)	Post: 9.63 (0.24)
Feeding mode	0.13	0.88	Follow-up: 9.24 (0.23)	Follow-up: 9.64 (0.24)
Cohort	4.60	0.04		
Baseline sleep	130.29	<0.0001		
<i>Infants' daytime sleep duration</i>				
Study group	0.01	0.93	Baseline: 6.65 (0.30)	Baseline: 6.22 (0.31)
Time	17.18	<0.0001	Midpoint: 5.48 (0.30)	Midpoint: 5.02 (0.31)
Group-by-time interaction	2.88	0.04	Post: 4.26 (0.30)*	Post: 5.21 (0.31)*
Feeding mode	3.05	0.05	Follow-up: 3.65 (0.30)	Follow-up: 3.67 (0.31)
Cohort	3.83	0.05		
Baseline sleep	141.47	<0.0001		
<i>Infants' night wakings</i>				
Study group	0.43	0.51	Baseline: 2.58 (0.16)	Baseline: 2.40 (0.17)
Time	8.52	<0.0001	Midpoint: 2.17 (0.16)	Midpoint: 2.12 (0.17)
Group-by-time interaction	1.33	0.26	Post: 1.89 (0.16)	Post: 2.07 (0.17)
Feeding mode	2.64	0.08	Follow-up: 1.49 (0.16)	Follow-up: 1.91 (0.17)
Cohort	0.14	0.71		
Baseline wakings	73.91	<0.0001		
<i>Parents' nighttime sleep^a</i>				
Study group	1.93	0.17	Baseline: 6.10 (0.21)	Baseline: 6.08 (0.22)
Time	4.38	0.005	Midpoint: 6.31 (0.21)	Midpoint: 6.52 (0.22)
Group-by-time interaction	0.97	0.41	Post: 6.57 (0.21)	Post: 7.01 (0.22)
Feeding mode	1.13	0.33	Follow-up: 6.80 (0.21)	Follow-up: 7.05 (0.22)
Cohort	0.01	0.93		
Baseline sleep	177.49	<0.0001		
<i>Parenting satisfaction</i>				
Study group	2.58	0.11	Baseline: 37.68 (0.75)	Baseline: 37.60 (0.78)
Time	3.35	0.02	Midpoint: 38.44 (0.76)	Midpoint: 37.13 (0.79)
Group-by-time interaction	1.87	0.14	Post: 39.68 (0.75)	Post: 39.11 (0.80)
Feeding mode	1.96	0.15	Follow-up: 39.89 (0.75)*	Follow-up: 37.21 (0.80)*
Cohort	0.15	0.70		
Baseline satisfaction	239.22	<0.0001		
<i>Parenting self-efficacy</i>				
Study group	0.00	0.96	Baseline: 29.95 (0.73)	Baseline: 29.49 (0.75)
Time	2.05	0.11	Midpoint: 30.73 (0.73)	Midpoint: 31.52 (0.76)
Group-by-time interaction	1.21	0.31	Post: 31.53 (0.73)	Post: 30.49 (0.77)
Feeding mode	0.22	0.80	Follow-up: 30.92 (0.73)	Follow-up: 31.75 (0.76)
Cohort	0.11	0.74		
Baseline efficacy	208.48	<0.0001		

Notes: ^aFor the main analyses of parents' nighttime sleep duration, we used the parent sleep duration indicator as recommended by Pittsburgh Sleep Quality Index scoring guidelines, but for the means in the text and in the table, we used parents' actual sleep reported in hours for interpretability. The best fitting (and selected) error structures were as follows: Toeplitz for infants' total, nighttime, and daytime sleep duration and parenting self-efficacy and autoregressive for infant night wakings, parent sleep, and parenting satisfaction. Bolding indicates overall group, time, or group-by-time effect (or covariate) was statistically significant. The test of whether the sleep intervention significantly changed the outcome of interest over time relative to the control group is indicated by the p-value for the group-by-time interaction. Asterisks indicate comparisons of least squares means at specific time points that reached statistical significance: *p<0.05, **p<0.01.

Parent Sleep

Parents' nighttime sleep duration tended to be higher in the intervention group, but group differences did not reach statistical significance. At the end of the intervention at infant age 4 months, average parental hours of sleep were: Control 6.58 ± 1.29 ; Intervention 7.01 ± 1.29 ; $p=0.06$.

Intervention Effects on Aspects of Parenting

Parenting Satisfaction and Self-Efficacy

There were no significant between group effects or group-by-time interactions related to parenting self-efficacy or satisfaction. Of note, parenting satisfaction increased in both groups over time ($F=3.35$, $p=0.02$). These statistics represent the time effect across groups, meaning that parenting satisfaction increased in both the sleep intervention group and the control group, with no significant group difference in this increase. While the overall group-by-time interaction was not significant ($p=0.14$), examination of least squares means showed that parenting satisfaction increased from baseline to post-intervention (infant age 4 months) in both groups, with the sleep group then experiencing a decline at follow-up (7 months), resulting in a between-group difference at the follow-up time point. Between-group differences in parenting self-efficacy were not significant at any time point. Full results from all marginal models are shown in Table 4.

Discussion

Results from this study demonstrate that an online sleep intervention increased daytime and total sleep among young infants with potential to also impact parent sleep duration. This study was successful in engaging the majority of enrolled participants in an interactive online intervention to support new parents with early infant sleep. Retention and satisfaction with the online intervention content were high, with parents' perspectives also providing ideas for future intervention refinement.

While prior evidence specifically aiming to promote sleep early in infancy via online methods is limited, effects of the present intervention were consistent with the available evidence, including the review by Crichton and Symon which showed that it is possible to impact infant sleep before age 6 months, with particular support for studies that focused on supporting infants' developing abilities to self-settle.⁶ Mindell et al's interventions,⁸ which consisted of personalized online feedback with or without promotion of a bedtime routine over 3 weeks, also affected infants' nighttime sleep, including latency to sleep onset, night wakings, and sleep continuity, as well as parent sleep duration and mood. In Mindell et al's study, children were 6–36 months old during the intervention, and at 1 year follow-up, effects of the online interventions were maintained in analyses of within-group change, with improvements also observed in the control group.⁹ The improvements in nighttime sleep in both groups illustrates changes in sleep that are expected to occur with developmental time. Yet the earlier group differences in sleep could be meaningful if these improvements in infant sleep have benefits in other domains of growth and development or for other family members.

Parent sleep and mood were impacted in the study by Mindell et al.⁸ Other effects were primarily in the realm of children's nighttime sleep, which may be more relevant than daytime sleep in a study with older infants and toddlers. Yet in the INSIGHT Study, in which infant sleep messages started within the first month after birth, effects on infant sleep were also primarily at night.⁴ In the present study, there were differences in total infant sleep by age ~4 months, but the differences seemed to be driven by effects on daytime sleep. It is possible that some of the specific lessons in the present intervention contributed to effects on daytime sleep (eg, lessons on naps and developmentally appropriate wake times between naps). That said, we did observe a difference in nighttime sleep that, while not statistically significant, was of a small effect size and in a consistent direction with impacts on daytime and total sleep. Future research could shed light on whether effects observed in the present study may be enhanced through additional support related to nighttime sleep or whether results look different when incorporating objective sleep measures, such as actigraphy, given that parents may not be able to report nighttime sleep as accurately as daytime sleep if sleeping themselves.

It is unclear whether the group differences in the present study are greatest at post-intervention and dissipate thereafter due to the timing of the intervention (ie no further support is provided after the post-intervention time point) or due to developmental changes. It is possible that impacts on daytime sleep lessen as a shorter percentage of

the infant's total sleep time occurs during the day as they grow older naturally. Differences in nighttime sleep continued to be in the expected direction through follow-up but did not reach statistical significance. Future research that extends the length of the sleep intervention could shed light on the potential for longer lasting impacts. Nevertheless, there is the potential for positive benefits to stem from lengthened infant sleep duration earlier in infancy. For example, in the INSIGHT Study, effects on infant sleep were attenuated by age 1 year, but impacts of the intervention were observed later in other domains, including child behavior¹⁶ and weight status.¹⁷ Current findings suggest that the observed effects on early infant sleep duration may extend to benefit parent sleep duration.

With regards to parenting satisfaction and self-efficacy, no specific effects of the sleep intervention emerged during the intervention period despite increased sleep. Parenting satisfaction increased in both study groups overall, which could have been related to the support provided to new parents in both study groups and/or changes that occur with infant development. These explanations cannot be parsed out in the context of the current study; more research is needed to understand potential impacts of this intervention approach on aspects of parenting during the intervention and afterward, given the group difference in parenting satisfaction that emerged after the interventions' conclusion.

It is important that early efforts to support infant sleep are developmentally appropriate and also acceptable to parents and caregivers. Implementation data support the idea that both study groups felt supported by and enjoyed their assigned intervention program. Most participants accessed intervention materials and found them useful. Parents' comments also revealed ways to improve the experience, such as providing the book in multiple formats and working to increase engagement in the online groups. In future work, in addition to posting informative videos and infographics, moderators could regularly post specific prompts to encourage more interaction in the groups. The similar implementation findings between the intervention and control groups suggest that the general baby care intervention, while not the focus of the study, was useful for participants.

Limitations of the present study include that sleep time was self-reported, with no follow-up after 7 months of age. Future research could incorporate more objective assessments and longer follow-up periods with potentially longer intervention support. In addition, given homogeneity in the present sample with regards to education level, future research in additional sociodemographic groups is needed. The present results may not be generalizable to families with lower education levels; we also cannot generalize these results to families with infants born prematurely or multiples, given exclusion criteria. Our study sample did include both male and female infants, with half the sample identifying as a race/ethnicity other than non-Hispanic white, which supports the potential to recruit a diverse sample of participants into this type of study. Given disparities in healthy sleep outcomes¹⁸ and a lack of representation of diverse populations in pediatric sleep intervention research,¹⁹ future research with this intervention approach should consider impacts in under-represented populations.

Conclusion

This online intervention designed to support new parents with infant sleep early in infancy showed improved total sleep time in infants, with evidence of consistent impacts on parent sleep in the intervention group. Follow-up analyses suggested that effects on total sleep may have been driven by effects on daytime naps, and that effects on infant sleep were significant particularly at the end of the intervention period. Findings support the feasibility and acceptability of this online intervention delivery model. Participants' engagement, as well as the diversity of the sample and high retention rates, support continued examination of an interactive online intervention as a promising approach for supporting healthy infant sleep development from the start. Future research could shed light on the potential to impact nighttime sleep and for longer-term impacts on sleep and other aspects of health and well-being.

Data Sharing Statement

Deidentified quantitative data can be provided by the corresponding author upon reasonable request and after analyses planned by the study team are completed.



Ethics Approval and Informed Consent

This study was approved by the University at Buffalo Institutional Review Board (Study #5999), and all participants completed informed consent prior to enrollment. The study complies with the Declaration of Helsinki.

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Alexis Dubief, MBA, worked collaboratively with the study team on intervention materials. Working from an outline of intervention content generated by the Principal Investigator (PI), Ms. Dubief created infographics and delivered video content in and moderated the sleep intervention groups. The PI approved the final products. Study staff were present in all online groups. The study team would also like to thank Sara Tauriello, MS; Kristen Kibler, BS; and Rocco Paluch, MS, for their contributions.

Author Contributions

SAF contributed to study conception and design, study execution, and data analysis and interpretation and led the drafting of the manuscript; JG contributed to study design, study execution, acquisition of data, and data analysis and drafting of the manuscript; ABH and JSS contributed to study conception and design and provided critical feedback on the manuscript; and VG contributed to study execution, acquisition of data, and provided critical feedback on the manuscript. The authors have approved the final version of the manuscript for submission and agree to take responsibility for the contents of the article. All authors agreed on the journal to which the article would be submitted.

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Disclosure

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