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SCIENTIFIC INVESTIGATIONS

Improving Sleep for Hospitalized Antepartum Patients: A Non-Randomized Controlled Pilot Study

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Study Objectives: To evaluate feasibility and efficacy of a hospital-based protocol for improving sleep in high- risk antepartum patients.
Methods: Sleep measures were compared during 1 week of hospitalization before and after implementing a Sleep Improvement Protocol for Antepartum Patients (SIP-AP). A non-randomized convenience sample of usual care controls was compared to a subsequent intervention sample after the protocol was implemented. Women were eligible if they spoke English, were medically stable, pregnant for at least 20 weeks, and hospitalized at least 24 hours; 25 pregnant women had sufficient data for analyses (11 controls, 14 intervention). Sleep was assessed in 3 ways: the Pittsburgh Sleep Quality Index was completed after obtaining consent to estimate sleep quality prior to hospital admission; sleep diary completed each hospital day; and General Sleep Disturbance Scale completed at 7 days or prior to hospital discharge. Symptoms that could affect sleep were assessed with the Memorial Symptom Assessment Scale.
Results: Both groups recorded similar sleep duration (7 hours) but the intervention group had fewer symptoms and significantly (P = .015) lower sleep disturbance scores (53.1 ± 14.5) than controls (71.9 ± 18.8). Participant feedback about the intervention was positive, although adherence to components of the intervention protocol was variable.
Conclusions: This pilot study provides evidence of the feasibility and preliminary efficacy of the SIP-AP intervention for reducing symptoms and improving sleep of antepartum patients during hospitalization. Further detailed evaluation of specific components of this protocol is warranted, and other types of hospitalized patients may benefit from unit-based modifications to this SIP-AP protocol.
Keywords: antepartum, inpatient, intervention, pregnancy, sleep hygiene
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INTRODUCTION

Sleep disturbance is a common complaint for women during pregnancy.[1–5] Poor sleep and short sleep duration have been associated with risk for preterm birth and cesarean delivery.[6–9] When a pregnant woman is hospitalized for a high-risk issue that threatens the fetus or her own health, her sleep becomes more problematic because of worry, stress, and fear,[10,11] and more fragmented because of the unfamiliar hospital environment with a strange and uncomfortable bed, excess light, and noise exposure at night.[12] For the health of the mother and fetus, hospitalization is likely to continue for weeks until birth occurs. Yet, the hypnotic agents often prescribed for hospital patients may not be advisable for antepartum patients due to potential adverse effects on the fetus. Although relatively few behavioral interventions are available to pregnant women, studies have tested exercise,[13] mindful yoga,[14] guided imagery,[15] massage,[16,17] and drinking herbal tea[18,19] to facilitate relaxation to improve sleep during pregnancy. No studies were found that tested these types of interventions with hospitalized antepartum patients.

Cognitive behavioral approaches for managing chronic insomnia have been shown to be effective for older adults,[20] shift workers,[21] and pregnant women.[22] This type of approach includes aspects of healthy sleep behaviors known as sleep hygiene, but the emphasis is placed on cognitive restructuring, stimulus control, and restricted time in bed. This can require weeks to achieve noticeable improvement in sleep outcomes. Hospitalized patients do not necessarily have chronic insomnia and are not likely to see benefits from these longer term behavioral approaches while hospitalized. Furthermore, some patients are on strict bed rest and cannot comply with restricting their time in bed and require as much rest as possible regardless of time of day. What is needed is a more immediate approach that places emphasis on sleep hygiene and how patients can manage their sleep within the hospital environment. Thus, the purpose of this study was to assess the feasibility

BRIEF SUMMARY
Current Knowledge/Study Rationale: Women hospitalized for a high-risk pregnancy are vulnerable to poor sleep due to the combination of pregnancy-related sleep disturbance and environmental disturbances common in the hospital setting. Although interventions to optimize sleep for hospitalized antepartum patients are needed, little research has been conducted.
Study Impact: This pilot study demonstrated feasibility and potential efficacy of a behavioral intervention protocol that includes components of sleep hygiene and cognitive behavioral therapy, for improving the sleep of antepartum hospitalized women. Further cost-benefit evaluation is warranted.

Table 1—Sleep BETTER hospital kit for antepartum patients.

Sleep BETTER hospital kit contents
From Nursing Station to be returned to Nursing Station:
1. 8.5 × 11 Velcro laminated door sign with sticky notes to write in patient's preferred wake time
2. 8.5 × 14 laminated Sleep BETTER sign for room bulletin board
3. Fan with D batteries (4)
4. White noise machine (set to "cool fan" noise and lowest setting) with AA batteries (4)
5. Choice of small book with book marker (or crossword or sudoku puzzle book)
From Nursing Station for patient to keep and use as directed:
6. 1 clear cosmetic bag with the following: note pad, pen, eye mask, ear plugs (4), nasal strips (4), scented ("day's end" wax melt cube) sachet*
*If not contraindicated, lavender sachet can be used but risk of contractions is noted on some websites.

and efficacy of a hospital-based sleep hygiene intervention, modified from prior sleep behavior intervention strategies to improve sleep among pregnant and postpartum women in their home environment.[22,23] This intervention approach was based on the Theory of Symptom Management[24] and Model of Impaired Sleep,[25] and was designed to combine patient education, hospital staff education, and provision of specific items and visual cues to provide more immediate improvement in sleep within the hospital setting. It was hypothesized that the hospital-based intervention would be feasible, and that antepartum patients who received the intervention would adhere to the protocol and have better sleep during hospitalization compared with similar patients who did not receive the intervention.

METHODS

In this non-randomized pilot study, sleep quality was first assessed in a control sample of antepartum patients receiving usual care during a 3-month period prior to introducing a sleep improvement protocol (SIP) intervention for antepartum patients (SIP-AP). Recruitment of the intervention group of antepartum patients occurred over the next 3 months. Both groups were recruited from the same hospital maternity unit that consisted of private rooms located within the same unit. The study was approved by the institution's Committee on Human Research. Informed consent was obtained from each participant. There was no monetary incentive for participation, but all participants in the intervention group were allowed to keep their sleep hygiene kit items.

Participants

For this feasibility pilot study, any hospitalized woman admitted to the maternity unit was eligible for participation if she was pregnant at a minimum of 20 weeks gestation with a viable fetus, a high-school graduate at least 18 years of age, able to read and write English, in stable condition with no other health complications, and hospitalized for at least 24 hours prior to being approached for recruitment into the study. After informed consent, the control group received usual care and a research packet containing questions about demographics, pregnancy history, sleep, and symptoms. A sleep diary with instructions for completion over the next 7 days was also included in the packet. The final sample of controls included 11 women who completed sleep questionnaires and a daily sleep diary over 7 days or until birth or hospital discharge. Of the 30 eligible women approached during a 3-month time frame, 20 consented (67%) and 11 had a minimum of 2 nights of data for analysis in the control group.

The intervention group met the same eligibility requirements, and was recruited and consented during the final 3-month period. The intervention group received usual care, written sleep hygiene information, and the Sleep BETTER hospital kit (**Table 1**). Of the 28 eligible women approached during this 3-month period, 19 consented (68%) and 14 had a minimum of 2 nights of data for analysis in the intervention group. Reasons for incomplete data from participants included unplanned early hospital discharge or labor and delivery within 48 hours of hospitalization.

Intervention Protocol

After completing data collection on control group participants during a 3-month period, there was a 1-month break in recruitment. During this break, the intervention protocol was reviewed and refined based on any sleep-related comments from control participants about their experience in the hospital. Staff nurses participated in information sessions about the study and helped to tailor the final content of the sleep information and content in the sleep hygiene kit to their patient population. Finally, nursing staff were oriented to the protocol and sleep hygiene kit items during a staff meeting and informational handouts were distributed and posted on the unit.

The hospital-based SIP-AP consisted of a laminated set of instructions posted by the nurse in the patient's room, a "do not disturb" door sign to be posted outside the patient's room, and an itemized sleep hygiene kit that also contained instructions for the patient.

The SIP intervention is based on educating patients about general principles of sleep hygiene and cognitive behavioral therapy for insomnia. The Sleep BETTER educational component comprised 6 brief topics: (1) bedroom environment, (2) exercise, (3) tension, (4) time in bed, (5) eating, and (6) rhythm (**Table 2**). The typical cognitive behavioral therapy approach is designed for chronic insomnia and requires weeks to implement before improvement is noted. Because these women did

Table 2—Six components of the Sleep BETTER educational program.

Bedroom	Light, noise, and temperature in the room affect your sleep. Try the comfortable **eye mask** and **ear plugs** in your sleep kit. White noise is very effective in blocking hallway noise. Your private bathroom may have a fan you can leave on at night for a source of white noise. Ask your nurse for a battery-operated fan or sound machine. The **fan** also keeps you cool and helps with nausea. The **sound machine** should be on the lowest possible volume. Try the "wind" setting first, avoid the water sounds (ocean, thunder showers, rain) if you are having frequent urination.
Exercise	Some daily activity is important for a good night's sleep. Ask your health care provider what physical activity you are allowed to do. If you are on bed rest, a physical therapist may be consulted about exercises you can do while in bed.
Tension	Reduce tension with relaxing activities in the evening to help you fall asleep. Relaxing activity can be reading a novel (not a murder mystery!) or doing a crossword puzzle. Ask your nurse for some reading material or puzzle book. Visualize lying on a sandy beach—feel the sun, feel your head resting on the beach towel, feel the warm sand on your legs and toes, listen to the waves. Your cell phone may have a relaxation app you can try, or use the relaxing options on your sound machine. Check your comfort level—it is hard to relax if you aren't physically and mentally comfortable. Go through this list with your doctor or nurse: Congested? Try a **nasal dilating strip** from your sleep kit. Heartburn? Ask your doctor if an order for antacids can help. Worried? Schedule your worry time after dinner and at least 1 hour before bed. Use the **pen** & **note pad** in your sleep kit to write down questions and concerns that arise during the night so you can let them go until morning. Leg cramp? Point toes toward your chin to stretch the leg muscle for fast relief. Restless legs? Gentle massage, warm bath; ask nurse or doctor about an alternating pressure device for your legs or alternating pressure mattress for the bed.
Time trying to sleep	Not everyone needs 8 hours of sleep at night, but you should allow at least 8 hours for sleep. Then, when the time comes, you have the necessary rest and energy for giving birth. Ask the nurse or doctor to place a do-not-disturb sign: "Trying to Sleep BETTER til…[time]" on your door with a **sticky note** from your sleep kit to indicate an agreed time to check in with you.
Eating and drinking	A light protein snack or warm milk can help you relax and sleep better. Ask for crackers, peanut butter, yogurt, or other comfort food to have at your bedside. Avoid caffeine (chocolate, cola, coffee, tea) at night. Decaffeinated herbal tea can be soothing.
Rhythm	A consistent schedule for day/light and night/dark is important for your brain's sleep chemistry and better sleep. Get light exposure from your window during the day. Avoid stimulating light at night. Light from monitors is not noticeable during the day, but is very bright during the night—ask the nurse to cover monitors with "chux" pad. You can also wear the comfortable eye mask in your sleep kit. Help tell your brain when it is dark and time for sleep—turn off your TV, cell phone, and other unnecessary light sources when you are ready to go to sleep.

not have chronic insomnia and may have strict orders for bed rest, specific components of cognitive behavioral therapy were modified. Cognitive behavioral strategies for dealing with stress and worry were tailored to the hospitalized antepartum population. Regardless of the patient's current sleep efficiency, time in bed was not restricted as it would normally be in cognitive behavioral therapy; rather, emphasis was placed on prioritizing time for sleep for patient health and wellbeing.

Materials included in the Sleep BETTER hospital kit were a written instruction sheet, a laminated version with maternity-specific visual cues to post in the patient's room, a laminated sign to post on the patient's door, and a kit with tangible items referenced in the written instructions. In addition to the 7-day sleep diary, participants in the intervention group also documented their daily use of the 6 components of the intervention protocol.

Measures

Participants provided brief demographic and pregnancy information (eg, age, race/ethnicity, education, employment, reason for hospitalization, parity). They completed a daily sleep diary to record their bed times, wake times, and times when sleep was disrupted as well as ratings of sleep quality and estimates of sleep duration. Sleep quality ratings in the daily diary were on a scale of 1 (very poor) to 6 (excellent). The sleep diary was completed during each day of hospitalization for up to 7 days. Data from the sleep diaries for the control group were examined for sleep issues, symptoms, and reasons for poor sleep in the hospital that then informed the final content for the SIP-AP intervention's educational component and sleep kit items. In addition to the daily sleep diary, all participants completed standardized measures of sleep and symptoms.

Pittsburgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI) is a 19-item self-report measure of sleep quality.[26] The PSQI was administered on day 1 to reflect participants' sleep quality over the past month prior to hospitalization. The 19 items are analyzed into 7 components with a range from 0 to 3 such that final PSQI sleep quality scores range from 0 to 21. A score above 5 is indicative of poor sleep quality in the general population. The PSQI also includes self-reported bedtimes, wake times, and hours of sleep per night for estimates of habitual time in bed and habitual sleep duration. The PSQI also includes a supplemental item related to loud snoring. The Cronbach alpha coefficient for the 7 components in this sample was 0.65.

General Sleep Disturbance Scale

The General Sleep Disturbance Scale (GSDS) is a 21-item self-report measure of sleep disturbance during the past week.[27] It was completed on day 7 of study participation, or prior to discharge if before day 7, as an estimate of sleep disturbance during the hospitalization. Each item is rated on a scale from 0 (no days) to 7 (every day). GSDS total scores can range from 0 (no sleep disturbance) to 147 (severe sleep disturbance). Scores above 42 are indicative of disturbed sleep in populations of women who work shifts,[27] women infected with the human immunodeficiency virus,[28] and women in treatment for breast cancer.[29] The Cronbach alpha coefficient in this sample was 0.72.

Memorial Symptom Assessment Scale

The Memorial Symptom Assessment Scale (MSAS) was used to assess the participant's symptom experience during the past week[30] and was completed on day 7 or prior to discharge if before day 7. Symptoms such as pain, worry, or nervousness, and distress related to these symptoms, can interfere with sleep at night. The SIP-AP intervention was designed to address many potential symptoms associated with poor sleep quality. The MSAS evaluates not only the occurrence, but also the frequency, severity, and distress of each symptom using 4- or 5-point Likert scales. Because of the known increased prevalence of insomnia[31] and restless legs syndrome[32–35] over the course of pregnancy, 4 items were added after the MSAS item on "difficulty sleeping" to address specific criteria for restless legs syndrome (Willis-Ekbom disease) and 3 specific dimensions of insomnia (difficulty falling asleep at bedtime, problems staying asleep during the night, and problems staying awake during the day). For this feasibility study, only occurrence and distress were evaluated for relevance to the SIP-AP protocol. The total number of original MSAS symptoms was calculated and could range from 0 to 17 symptoms. The mean distress score could range from 0 (no distress) to 4 (high distress).

Feasibility

Feasibility was evaluated in 4 ways: (1) how long it took to enroll patients; (2) how many were excluded based on failure to meet inclusion criteria; (3) how many remained hospitalized for a full week and extent of missing data; and (4) patients' use and satisfaction with each component of the sleep kit. Participants enrolled in the intervention phase of the study received the same measures for the same time periods. In addition to the daily sleep diary, intervention participants completed additional items in their diary each day to indicate which of the 6 components in the Sleep BETTER hospital kit they tried. If they tried a strategy, they were then asked to indicate how satisfied they were with how the strategy improved their sleep. Each component was rated on a 5-point scale with options of not at all (0), a little (1), somewhat (2), very (3), or extremely (4).

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences Version 22.0 (IBM Corp, Armonk, New York, United States). Participants with only 1 night of data (9 controls and 5 intervention participants) were excluded from analyses. Frequencies and descriptive statistics were used to check for normality and to summarize demographic and clinical characteristics for the 2 groups of patients. Sample characteristics for the 2 groups were compared using chi-square tests for categorical variables and Fisher exact tests were used for the symptom comparisons due to small cell sizes. Independent sample *t* tests or Mann-Whitney *U* tests were used as appropriate for comparisons of continuous variables. Repeated-measures analysis of variance (RMANOVA) was used to examine within-subjects changes over the seven nights by group. Daily measures were also averaged to obtain a mean value for each participant.

A 2-tailed alpha level of .05 was used for all statistical tests. A power analysis indicated that 25 participants per group would be needed to detect a medium-sized effect (Cohen $d = 0.50$) with 80% power and a 2-tailed alpha of .05. Given the small sample sizes for the final groups with complete data, effect sizes in standard deviation units (Cohen *d*) were calculated for group comparisons of sleep outcomes. A Cohen *d* of 0.50 was also considered the minimum effect size for establishing clinical relevance for the difference in sleep duration and GSDS scores between the 2 groups in this pilot feasibility study.[36]

RESULTS

Sample Characteristics

The 2 groups were not significantly different for any demographic variables (**Table 3**). For the entire sample, gestation averaged 29.0 ± 3.3 weeks and maternal age averaged 32.9 ± 6.8 years. Most of the participants (n = 18, 72%) were singletons, and there were 4 sets of twins and 3 sets of triplets. Height and weight were self-reported at prepregnancy and the current hospital admission values were used to calculate body mass index using the formula: weight (kg)/height $(m)^2$; means and standard deviation were 27.4 ± 8.0 and 32.7 ± 10.3, respectively. PSQI scores ranged from 3 to 15 (mean = 8.1 ± 3.6) and 68% (n = 17) scored above the cutoff point of 5. Both groups self-reported habitual sleep time that ranged between 5 hours and 9.5 hours (median = 6.9; mean = 6.9 ± 1.1 hours).

Intervention Outcomes

The outcomes for this feasibility study were sleep disturbance scores on the GSDS, daily sleep diary entries for sleep duration and quality, total number of symptoms experienced, and symptom distress scores that differed between control and

Table 3—Baseline characteristics of the participants.

Baseline Demographic Descriptors	Total Sample (n = 25)	Control Group (n = 11)	Intervention Group (n = 14)	Significance
Age (years), mean ± SD	32.9 ± 6.8	33.4 ± 7.9	32.5 ± 5.9	NS
Gestation (weeks), mean ± SD	29.0 ± 3.3	28.6 ± 3.6	29.2 ± 3.2	NS
Singleton pregnancy, n (%)	18 (72)	8 (72)	10 (71)	NS
Body mass index, mean ± SD				
Prepregnancy	27.4 ± 7.98	28.9 ± 7.4	26.1 ± 8.5	NS
Late pregnancy	32.7 ± 10.3	33.0 ± 7.8	32.4 ± 12.3	NS
Race/Ethnicity, n (%)				NS
Caucasian	18 (72)	8 (73)	10 (71)	
Latina	3 (12)	1 (9)	2 (14)	
African American	1 (4)	0 (0)	1 (7)	
Asian/other	3 (12)	2 (18)	1 (7)	
Employed, n (%)				NS
Full time/part time	11 (44)	5 (45)	6 (43)	
On maternity leave	7 (28)	3 (27)	4 (29)	
Not employed for pay	7 (28)	3 (27)	4 (29)	
Work nights, n (%)	4 (16)	2 (18)	2 (14)	NS
Pittsburgh Sleep Quality Index				
Global score				
Mean ± SD	8.1 ± 3.6	9.2 ± 4.0	6.8 ± 4.1	NS
Score > 5, n (%)	17 (68)	9 (82)	8 (57)	NS
Loud snoring once or more per week, n (%)	9 (36)	5 (45)	4 (29)	NS
Habitual time in bed (hours), mean ± SD	8.5 ± 1.1	8.6 ± 1.0	8.4 ± 1.2	NS
Habitual sleep duration (hours), mean ± SD	6.9 ± 1.1	6.8 ± 1.2	6.9 ± 1.1	NS

NS = not significant, SD = standard deviation.

Table 4—Intervention outcomes for antepartum hospitalized patients.

General Sleep Disturbance Scale	Control Group (n = 11)	Intervention Group (n = 12)	Significance
Mean ± SD	71.9 ± 18.8	53.1 ± 14.5	$t = 2.6$, $P = .015$
Range	41–97	34–80	$d = 1.15$
Median	76	48	
Score < 43	3 (27%)	8 (67%)	$\chi^2 = 3.6$, $P = .059$
Memorial Symptom Assessment Scale	**Control Group (n = 10)**	**Intervention Group (n = 12)**	**Significance**
Mean ± SD	8.3 ± 4.08	6.6 ± 4.08	$t = 0.99$, $P = .33$
Range	2–15	2–12	$d = 0.42$
Median	8.0	6.0	

SD = standard deviation.

intervention groups during 1 week of hospitalization. At the end of the week or prior to discharge, both groups reported in their sleep diaries that the most frequent reason for awakenings during the night was monitoring by the nursing staff, followed by noise in the hallway.

General Sleep Disturbance

The control group had high scores for sleep disturbance (mean GSDS = 71.7 ± 17.86). For the 6 women in the control group who completed all 7 days of the study, the GSDS score was similar (69.1 ± 17.29), indicating that incomplete data had little effect on the observed results. The women in the intervention group had significantly lower GSDS scores (53.1 ± 14.47) than controls (**Table 4**). For the 6 women in the intervention group who completed all 7 days of the study, the GSDS score was 47.4 ± 9.84, indicating that incomplete data also had little effect on the observed results (**Table 4**). The group difference in GSDS scores was significant regardless of whether the total sample was compared ($t = 2.65$, $P = .015$; effect size $d = 1.11$) or whether only those in the 2 groups who completed all 7 nights were compared ($t = 2.83$, $P = .018$; effect size $d = 1.61$). In addition, when participants were dichotomized by the GSDS cutoff point of 42 or less, as an indication of good sleep, 8 of the 12 women in the intervention group (67%) had good sleep compared with only 3 of the control participants (27%) (**Table 4**).

Figure 1—Self-reported sleep duration during hospitalization.

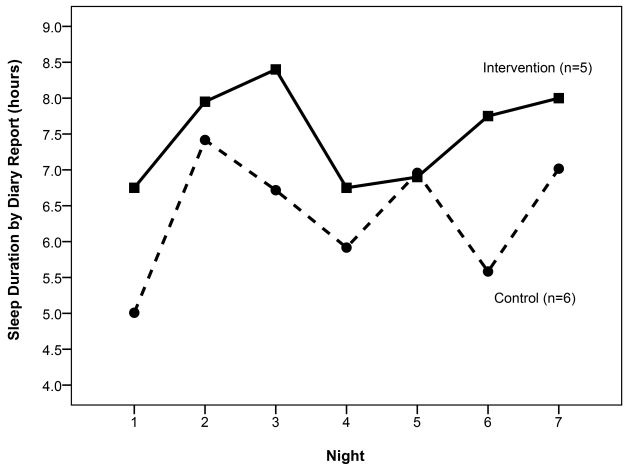
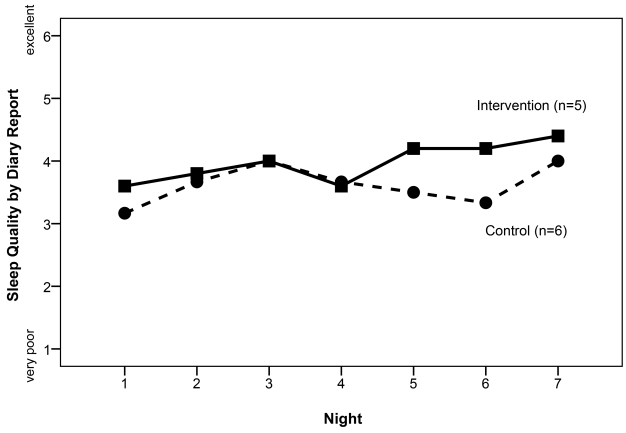


Figure 2—Self-reported sleep quality during hospitalization.



Daily Sleep Diary

In the total sample, diary-reported sleep during the night ranged over the 7 nights from 5.3 to 7.5 hours. For the 10 participants with complete data for all 7 nights, the intraclass correlation coefficient for total sleep time was .645. The shortest sleep duration was on night 1, when the control group recorded 5.4 ± 2.46 hours and the intervention group recorded 6.6 ± 2.12 hours in their diaries. The greatest difference between groups in sleep duration was on night 6 (**Figure 1**). Although RMANOVA results indicated no significant within-subject changes over the 7 nights, the between-group difference was statistically significant in this small sample ($F_{1,9}$ = 5.6, P = .042). Sleep quality followed a similar pattern (**Figure 2**), but there was no significant within-subject change over time, and no significant between-group difference ($F_{1,9}$ = 2.5, P = .149). RMANOVA also revealed no significant time or group differences in diary measures of sleep restfulness or satisfaction with sleep.

Symptom Experience

The SIP-AP protocol included information and sleep hygiene kit items that addressed ways to relieve or minimize symptoms or distress that could interfere with sleep. At the end of data collection, 10 of the 11 control participants completed the MSAS. Of the 17 symptoms on the MSAS, 90% of the control sample endorsed drowsy and difficulty sleeping, 80% endorsed low energy, and 70% endorsed nervous, sad, or worry (**Table 5**). Twelve of the 14 women in the intervention group completed the MSAS and symptoms were similar although less prevalent. Worry and difficulty sleeping were the most common symptoms (83.3%), followed by 68% who endorsed low energy or drowsy, and 50% who endorsed feeling sad (**Table 5**).

The MSAS total symptom score was not significantly different between groups (P = .33) but the control group experienced a mean and median of 2 more symptoms than the intervention group, and the effect size was almost one-half standard deviation units (d = 0.42). Both groups were similarly experiencing worry, yet 70% (n = 7) of the control group endorsed feeling nervous and only 33% (n = 4) of the intervention group endorsed that symptom. As seen in **Table 5**, this difference did not reach statistical significance in this small sample.

For symptoms of restless legs added to the MSAS, 3 women (1 control and 2 intervention women) endorsed an abnormal sensation or urge to move their legs that came on at rest and occurred in the evening, but only 1 indicated that it was relieved with movement. None of the insomnia-specific items added to the MSAS differed significantly by group (**Table 5**). However, there were trends that favored the intervention group: (1) difficulty falling asleep was endorsed by 80% of controls and only 58% of the intervention group; (2) difficulty staying asleep was endorsed by 90% of the control group and 75% of the intervention group; and (3) daytime sleepiness was more common (60%) in controls compared to the intervention group (42%).

The overall symptom distress score on the MSAS was higher for the control group (2.05 ± 1.95) compared with the intervention group (1.40 ± 1.04), but this difference in distress was not statistically significant. The only specific symptom that differed significantly (t = 2.12, P = .046) for its level of distress was daytime sleepiness (data not shown), in which the intervention group had less distress (0.08 ± 0.29) than controls (0.73 ± 1.01). Other distress scores had similar trends, but were not significantly different in this small sample.

Feasibility

Overall, implementation of this type of sleep intervention in the acute care environment was feasible. The time frame for data collection was constrained by the study design and access to 1 hospital unit. Rather than risk potential contamination of the intervention, the control group was enrolled prior to staff knowledge of the components of the intervention. Each 3-month enrollment period had more than a 50% response rate. During the 3-month control phase, 30 patients were eligible and approached to participate, and 20 consented (67%). In the intervention group, 28 patients were eligible and approached, and 19 consented (68%). The inability to speak English was the most frequent reason for exclusion. This was expected given the limited budget for this pilot study and lack of funds available for translation. The second most common reason for

Table 5—Frequency of symptoms on the Memorial Symptom Assessment Scale.

Memorial Symptom Assessment Scale Symptom	Control Group (n = 10) [a]	Intervention Group (n = 12) [b]
1 Pain	6 (60)	3 (25)
2 Lack of energy	8 (80)	8 (67)
3 Nervous	7 (70)	4 (33) [c]
4 Nausea	5 (50)	3 (25)
5 Drowsy	9 (90)	8 (67)
6 Numbness/tingling in hands/feet	3 (30)	3 (25)
7 Difficulty sleeping	9 (90)	10 (83)
Problems falling asleep at night	8 (80)	7 (58)
Problems staying asleep at night	9 (90)	9 (75)
Problems staying awake during day	6 (60)	5 (42)
Abnormal sensation or urge to move legs	1 (10)	2 (17)
8 Feeling bloated	5 (50)	4 (33)
9 Problems with urination	1 (10)	1 (8)
10 Shortness of breath	5 (50)	3 (25)
11 Sad	7 (70)	6 (50)
12 Sweats	3 (30)	4 (33)
13 Worry	7 (70)	10 (83)
14 Itching	2 (20)	3 (25)
15 Lack of appetite	4 (40)	3 (25)
16 Dizziness	2 (20)	2 (17)
17 Irritable	5 (50)	4 (33)

Values are presented as n (%). [a] = missing data from 1 control participant. [b] = missing data from 2 intervention participants. [c] = Fisher exact test, $P = .09$ (1-tailed).

exclusion was expected hospital discharge within 48 hours. The number of women who remained hospitalized for a full week was similar in both groups (6 per group; 30% to 32%), and the extent of missing data was also similar. Reasons for exclusion were expected, and response rates were similar in both groups. Feasibility would have been enhanced if more patients had stayed in the hospital for at least 7 days.

Feasibility of implementing the intervention and satisfaction with using each component of the sleep kit were also evaluated. Women who received the SIP-AP intervention and sleep kit remarked that both the fan and the white noise machine were helpful to decrease noise. The fan had the added benefit of providing cool air and alleviating the nausea experienced by the 3 intervention women who endorsed the symptom of nausea on the MSAS. Other helpful items in the sleep hygiene kit were the eye mask to block out light from the monitors and the white noise machine, which not only masked noise but fostered relaxation prior to going to sleep. One participant commented that the "room should be permanently equipped with white noise machines and ear plugs" whereas another commented that "the mask and white noise were very helpful but I still had GI [gastrointestinal] problems."

As seen in **Table 6**, not all 6 of the intervention components were used by all participants in the intervention group. The components most often used in the hospital setting were bedroom environment, tension, and time in bed. Patients were less likely to use the exercise, eating, and rhythm components, but commented that it was all very useful information. Exercises that could be done in bed were only tried by 5 women, and they were not particularly satisfied that it helped their sleep. This was also the case for the eating component. Half of the intervention group tried the rhythm component and were satisfied with it. One participant commented that she "would like to be able to control the lights from bed."

Table 6—Intervention components used and satisfaction ratings (n = 14).

SIP-AP Intervention Component	Component Used Any Night (%)	Very or Extremely Satisfied (%)
Bedroom	100	100
Exercise	33	33
Tension	100	100
Time	100	66
Eating	33	66
Rhythm	50	100

SIP-AP = Sleep Improvement Protocol for Antepartum Patients.

DISCUSSION

This pilot study demonstrated feasibility and preliminary efficacy of the SIP-AP intervention for improving antepartum sleep while in the hospital setting. The intervention was acceptable, and participants were satisfied with the components they were asked to try. Participants in the intervention group had similar symptoms and similar hours of sleep according to

their 7-day sleep diary, but overall sleep disturbance was significantly less than that in controls enrolled in the study prior to introducing the intervention on the hospital unit. Compared with sleep disturbance associated with worry and nervousness, sleep during pregnancy can be influenced by physiological factors (eg, nausea, restless legs) that are less amenable to the behavioral intervention structured into the six components described in the Sleep BETTER program.

Sleep duration in this sample of hospitalized antepartum patients was not optimal, even considering their self-reported habitual sleep time on the PSQI prior to hospitalization. Facco and colleagues[4] reported a mean of 7 hours sleep duration and PSQI scores > 5 for just over half (53.5%) of their sample of clinic patients with singleton pregnancy at 30 weeks' gestation. In our current sample of hospitalized patients at similar gestation, mean sleep duration on the PSQI was also 7 hours; however, 80% had PSQI scores > 5. Gallo and Lee[12] used wrist actigraphy to monitor sleep in 39 hospitalized antepartum patients and reported a median sleep duration of 7 hours. The current sample of hospitalized antepartum patients reported a similar median and mean of 6.9 hours in their sleep diaries.

It is often assumed that pregnancy sleep disturbance is related to discomfort or frequent urination, yet these hospitalized women reported low rates of pain and problems with urination. Maloni[10,11] found that antepartum patients on bed rest for preterm labor differed in the number of symptoms if they were singleton pregnancies (mean of 8 symptoms) compared with twins or multiples (mean of 22 symptoms). In our sample, the women with singleton pregnancies had 7.6 ± 4.0 symptoms and the women with multiple gestation pregnancies were similar with 8.4 ± 4.8 symptoms.

Some interventions that include behaviors to promote relaxation and counter negative thoughts in order to reduce nervous and worry symptoms for expectant mothers[37] may be promising. Because half the sample in this study was sleeping less than 7 hours, both habitually at home and while hospitalized, and because our finding supports other research findings for women at similar gestation, teaching about healthy sleep hygiene behaviors and stressing the importance of adequate sleep duration should occur early in pregnancy during routine prenatal visits. Although the symptoms that disrupt sleep may not change as a result of this intervention, the distress associated with these symptoms may be alleviated to some extent, which could improve sleep quality.

There are some notable limitations in this pilot study. Although we minimized group contamination and the threat to historical validity by recruiting each group during a brief 3-month time frame with only 1 month between groups, the overall sample was small and non-randomized. Our small sample precluded analysis of potentially confounding variables and is not representative of all childbearing women. The non-random assignment may have resulted in unmeasured systematic differences between participants enrolled during the control and intervention periods. As a result, it cannot be ruled out that the observed group differences in sleep were due to factors other than the intervention. Moreover, as anticipated, many of the participants were on bed rest and certain aspects of healthy sleep hygiene, such as avoiding prolonged periods in bed, were not stressed. Our intervention protocol was designed to take limitations such as this into account. For example, other ways for women to cue their bodies that it was time to sleep, such as darkness and quiet, were emphasized.

In this study, participants were not necessarily complaining about sleep in the hospital setting when they were invited to enroll in the study. It may be more effective to target the intervention specifically to women who are experiencing poor sleep. For example, intervening specifically with environmental noise reduction protocols would be more effective for patients who complain of difficulty falling asleep because of noise. However, in such a short and critical time frame during hospitalization, it may be more important to approach patients with a prevention model rather than a treatment model early after the critical event has stabilized. Although the use of an objective measure of sleep would strengthen the study outcomes, symptoms that include poor sleep are subjective phenomena and outcomes based on what participants experience may be more meaningful to the patient and thus likely to have higher adherence. This study did not include standardized assessments of obstructive sleep apnea, restless legs syndrome, or insomnia. These types of conditions may have influenced the patients' response to the intervention, but no diagnoses of other health problems were noted on hospital admission.

Finally, without additional participant burden, evaluation of the intervention's feasibility could be strengthened in future studies by more detailed documentation of how each intervention component was utilized by the participants. Experiences for this sample were primarily reflective of a 7-day period in the hospital environment, which may be less stable than the home environment, and may differ by the room location within the hospital unit. Finally, participants were not recruited until after they had spent their first night in the hospital unit, and sleep did continue to improve later in the week compared to the first night of self-reported sleep diary. This would suggest that some level of adaptation to the hospital environment is occurring during the week-long hospitalization data collection period.

In conclusion, this pilot study demonstrated the feasibility and potential efficacy of the SIP-AP behavioral intervention protocol, which includes components of sleep hygiene and cognitive behavioral therapy, for improving the sleep of antepartum hospitalized women. The 3 components used most in the hospital setting were bedroom environment, tension, and time in bed. Patients were less likely to use the other 3 components of exercise, eating, and rhythm, but commented that it was all very useful information. This SIP-AP protocol has high potential as a convenient and noninvasive intervention without adverse side effects that hospital staff can implement on their unit. Further evaluations of each component of the intervention, its costs and acceptability, and modifications for other types of hospital units, are warranted for improving sleep in other populations of hospitalized patients.

ABBREVIATIONS

GSDS, General Sleep Disturbance Scale
MSAS, Memorial Symptom Assessment Scale
PSQI, Pittsburgh Sleep Quality Index
RMANOVA, repeated measures analysis of variance

SD, standard deviation
SIP, sleep improvement protocol
SIP-AP, sleep improvement protocol for antepartum patients

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