A Sleep Promotion Toolkit for Hospitalized Patients

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1. Structured Abstract
Purpose: To inform the development of a sleep promotion toolkit (SLEEPkit) for hospitalized patients by conducting iterative refinement and pilot evaluation.
Scope: Inpatient sleep disturbance has been linked to clinically relevant and detrimental outcomes such as delirium and falls. Routine assessment, open dialogue with the patient, collaborative care planning, and tailored interventions, are key to patient-centered care to improve sleep for hospitalized patients. Interventions using health information technology hold potential to address these key issues of inpatient sleep promotion.
Methods: Qualitative methods within a standardized iterative participatory approach by working with stakeholders supported the refinement of the SLEEPkit. A randomized control trial in 126 patients was conducted to evaluate the effectiveness of SLEEPkit on patient sleep assessed by the PROMIS Sleep Disturbance and the actigraph. Semi-structured interviews were conducted to seek feedback on SLEEPkit focused on perceived usefulness, ease of use, user control, implementation, and maintenance.
Results: Patients and clinicians perceived that SLEEPkit empowered patient and supported patient-centered care. No statistical differences were observed in patient sleep between intervention group and control group receiving usual care. Future investigation should optimize user engagement, include clinician interface to engage providers, and promote sleep at both unit setting and individual levels.
Key Words: Inpatient sleep; sleep promotion; health information technology; acute care hospital; patient-centered care

2. Purpose
Aim 1: To iteratively refine a patient-centered sleep promotion toolkit (SLEEPkit) for hospitalized patients.
Aim 2: To pilot evaluate the SLEEPkit, including its effectiveness on patient's sleep during hospitalization, as well as the perceived usefulness, ease of use, user control, implementation, and maintenance in the acute care hospital setting.

3. Scope

Sleep is a fundamental human need for survival, health, and well-being [1]. The importance of sleep does not diminish just because a person is admitted to the hospital. In fact, a person's need for sleep is greater during periods of illness, and adequate sleep is critical to optimizing recovery [1]. Patients themselves are concerned about the inability to get restorative sleep while in the hospital setting [2]. Approximately 50% of general medical patients complain of sleep disruption [2,3], and this percentage can be even higher among those in the intensive care units [4,5]. Sleep disturbance can also worsen other symptoms such as fatigue, pain, and depression, which are commonly experienced by hospitalized patients [6,7]. Furthermore, inpatient sleep disturbance and medications prescribed in an attempt to improve sleep, have been linked to clinically relevant and detrimental outcomes such as delirium [8,9] and falls [10,11]; both of which are known risk factors for morbidity, mortality, prolonged hospital stays, and increased healthcare costs. Finally, poor sleep in the hospital may lead to chronic sleep disruption even after hospital discharge [12].

Despite the growing evidence linking sleep to outcomes which are critical to patient safety and healing, sleep is not valued as a recovery modality during hospitalization. Clinicians' attitudes are reflected in the following comment: "*We joke that you [the patient] don't come to the hospital for a good night's sleep!* [13]" Although guidelines may recommend an assessment of sleep, the lack of clear methods of improving sleep mean that, in practice, clinicians rarely inquire about sleep. Inpatient pharmacological sleep-aid use remains common, even in older patients in spite of a warning of high risk of side effects including delirium and falls, again reflecting the perceived lack of options by clinicians to improve sleep [14].

As a basic human need, inpatient sleep should be emphasized as we seek to improve care quality and safety through patient-centeredness [15]. In our previous work we found that routine assessment, open dialogue with the patient, collaborative care planning, and tailored interventions, are key to patient-centered care to improve sleep for hospitalized patients [13]. A recent nationwide multicenter study in Netherlands demonstrated comprised sleep quantity and quality in hospitalized patients and called for interventions that target modifiable hospital-related sleep-disturbing factors [16]. One major challenge of inpatient sleep promotion is that there is no "one-size-fits-all" intervention as patients' sleep may be disturbed by different factors. Studies testing various non-pharmacologic sleep promotion interventions (e.g., daytime artificial light therapy, quiet time, white noise, relaxation techniques such as massage, music, and audiotaped guided imagery) in a general inpatient setting have provided overall insufficient to low strength evidence supporting those interventions [17]. These studies typically applied a specific intervention without seeking patients' input to identify or address what interfered with their sleep, which might have contributed to the limited overall success. For example, a study of eye masks to promote sleep may find little overall benefit if 1) some patients do not

perceive bright light as a barrier to sleep, or 2) if some patients do not accept the eye mask.

Interventions using health information technology (IT), which improve timely communication and facilitate information access for decision support, hold potential to address these key issues of inpatient sleep promotion. Funded by the Agency for Healthcare Research and Quality (1R21HS024330), my team developed and pilot evaluated a **sleep promotion tool kit (SLEEPkit)** for hospitalized patients. In Phase 1 of the project, we used an iterative participatory approach to support the refinement of the SLEEPkit. In Phase 2, we pilot evaluated the feasibility of using the SLEEPkit in the acute care hospital setting, and tested its effectiveness of sleep promotion using a small randomized clinical trial (RCT). Findings from study will guide further refinement of the SLEEPkit and inform the effect size of study outcomes for a future adequately powered RCT to evaluate the SLEEPkit application. Starting from a valid self-assessment for sleep and its disturbing factors during the previous night, the SLEEPkit can generate personalized tips to address the patient's specific need for sleep.

Basic features of SLEEPkit include:

How to access the SLEEPkit?

A downloadable app accessed from a smart phone or iPad device.

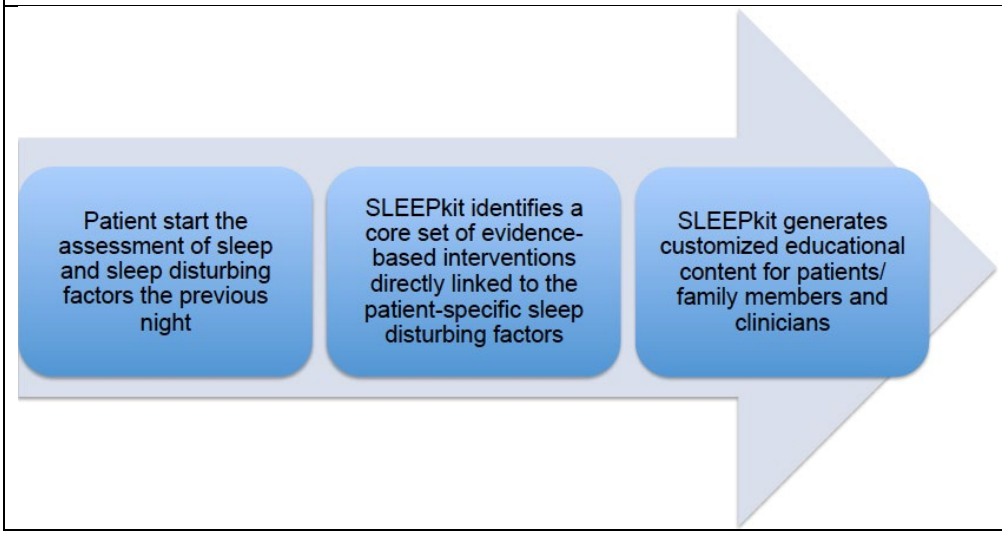
Who are the users of the SLEEPkit?

Because SLEEPkit is designed as an app downloaded to the patient's device, patient will be the primary user of the SLEEPkit. This is consistent with the self-assessment nature of sleep. Clinicians, primarily nurses, are able to review patient sleep and the tips of sleep promotion from the SLEEPkit on the patient's device at bedside. The goal is to encourage the communication of patient sleep and facilitate a discussion of sleep promotion at the patient bedside.

How does the SLEEPkit work?

The SLEEPkit aims to establish evidence-based linkages between routine sleep assessment and tailored interventions to improve sleep in acute care hospitals (Table 1).

Table 1: The workflow and aims of SLEEPkit

How does SLEEPkit work?	SLEEPkit aims to support
	• Routine sleep assessment • Individualized care plan and education for sleep promotion • Communication between patients and care providers • Patient-centered care • Patient empowerment

How can the SLEEPkit support patient-centered care?

1). Routine assessment for sleep and sleep disturbing factors (recommended on a daily basis) – to *facilitate routine sleep assessment in acute care hospital settings, and serve as the basis for individualized plan for sleep promotion*;

2). Patient to complete sleep assessment, and more likely, start the conversation of the sleep with his/her nurse at bedside – *to empower patient and afford patient a distinct voice in the decision making process demonstrated by assessment and care plan development;*

3). Tailored messages for both patients and clinicians – *to facilitate communication and the collaborative effort of sleep promotion.*

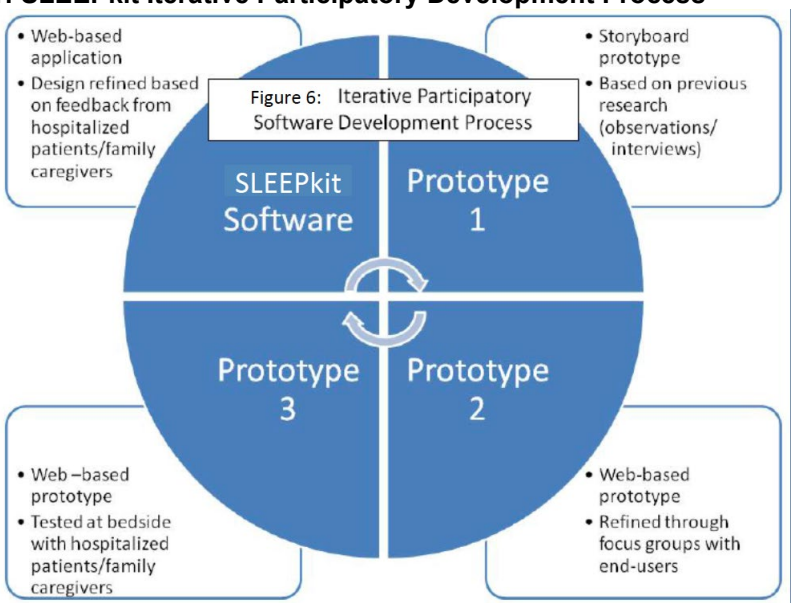
4. Methods

4.1. Aim 1: SLEEPkit Refinement

4.1.1. Iterative Refinement Process

Qualitative methods within an iterative participatory approach supported the refinement of the SLEEPkit (Figure 1). Feedbacks from stakeholders including patients, care partners, and clinicians were obtained throughout the development process via one-on-one interviews or focus groups. Focus groups were conducted in patients/ care partners and clinicians who served in the Patient/ Family Advisory Council, or the existing interdisciplinary professional practice committees at the Brigham and Women's Hospital. A semi-structured interview guide was used to focus and facilitate the interview process. Content analysis including data reduction, data display, and conclusion drawing were performed for each interview to derive topical codes to interpret the data.

Figure 1: SLEEPkit Iterative Participatory Development Process



4.1.2. Bedside Testing

Bedside testing for Prototype 3 was conducted in 20 patients. The inclusion criteria for patient participants were: inpatient admission on a patient care unit, older than 18, awake and alert, cognitively intact, able to understand and speak English, able to articulate observations regarding communication needs, and to be able to provide feedback on the SLEEPkit prototype. Purposive sampling will be used to ensure a diverse patient sample for bedside interviews and usability tests in terms of age, gender, education, and the level of comfort with technological interfaces. Consented patients participated in bedside interviews to validate the concept of using the SLEEPkit and to test the usability of Prototype 3. Each component of the user interface and associated content were reviewed. Each patient was provided with an opportunity to use and become familiar with the SLEEPkit. The facilitator asked each patient a series of questions to assess their ability to use the SLEEPkit prototype and locate key information. Four tasks were designed for the test, including 1) to assess sleep last night; 2) to find tips to help improve sleep; 3) to role-play with your interviewer (as if she were your nurse); and 4) imaging it's the next day, update your sleep assessment. Responses to the SLEEPkit prototypes and suggestions for improvement were documented. Recommendations based on the bedside usability testing were compiled and integrated in the final version of the SLEEPkit.

4.1.3. Sleep Disturbing Factors (FAIS Scale) and Sleep Promotion Tips Development

As part of the SLEEPkit development process, we developed the Factors Affecting Inpatient Sleep (FAIS) scale including 14 common sleep-disturbing factors in the hospital. Instead of including a comprehensive list of factors that could affect inpatient sleep, the FAIS is a brief tool covering the most significant sleep disturbing factors perceived by patients, that could be used to facilitate further discussion of sleep leading to individualized sleep promotion plan. Furthermore, we proposed strategies targeting both patients and clinicians to mitigate each factor on this scale, which may serve as customized education to support individualized sleep promotion interventions. Table 2 summarizes the methods and outcomes for the FAIS scale and sleep promotion tips development.

Table 2: Development of the Factors Affecting Inpatient Sleep (FAIS) Scale and Sleep Promotion Tips

Aims	Methods	Outcomes
FAIS Scale Development		
• 1) To identify factors that disturb patient sleep in the hospital – *Item Development and Validation*	• Literature review • Content analysis of interview data with clinicians and patients • Content validity test	• A 40-item survey evaluating the 40 sleep disturbing factors summarized in four categories was developed and validated
• 2) To select the most significant sleep disturbing factors perceived by patients – *Item Selection for Psychometric Evaluation*	• Survey collected from 105 hospitalized patients to evaluate the 40 sleep disturbing factors • The sleep disturbance scores on a numeric scale of 0 to 10 were reviewed	• 21 items selected from the original 40 items to be used for psychometric analysis
• 3) To psychometrically evaluate the FAIS scale with reduced items	• Psychometric evaluation using survey data from the remaining 21 items, including item analysis, principal components analysis, and internal consistency reliability	• A final scale including 14 items with 3 subscales which demonstrated psychometric adequacy
Sleep Promotion Tips		
• To propose strategies mitigating the sleep disturbing factors	• Literature review • Content analysis of interview data and written feedback of sleep promotion strategies collected from the survey • Iterative refinement process with input from patients and clinicians by focus groups	• A list of strategies suggested for both patients and nurses to mitigate each of the 14 sleep disturbing factors

4.1.4. SLEEPkit Icons Development

Icons were developed for each of the 14 factors on the FAIS scale. All icons were tested using standardized Content Validity Index (CVI) test to if the icon represents the concept, with the choices of 1 (strongly disagree), 2 (moderately disagree), 3 (moderately agree), and 4 (strongly agree). The final version of each icon had a CVI index at 3 (Moderately Agree) or 4 (Strongly Agree). An iterative refinement process with input from patients and clinicians was used to develop and finalize all icons built into the SLEEPkit.

4. 2. Aim 2: SLEEPkit Pilot Evaluation

4.2.1. The Effectiveness of the SLEEPkit on Patient's Sleep during Hospitalization

Hypothesis: We hypothesize the patients who use the SLEEPkit will have a greater change in the self-perceived sleep quality from the day of admission to the day of discharge, as measured by the PROMIS Sleep Disturbance,[7] compared to the patients who receive usual care for sleep. Secondary outcomes include objective sleep quality continuously monitored during hospital stay by the actigraph, daytime impairments related to sleep or sleep problems (measured by the PROMIS Sleep-Related Impairment[7]), common symptoms pertinent to sleep including pain, fatigue, anxiety, depression, anger, and cognitive function (measured by the PROMIS tools), use of pharmacological sleep aid, incidence of falls, delirium, and death, length of hospital stay.

Subject Selection: We recruited a total of 126 patients, randomized to the intervention group using the SLEEPkit, or to the control group receiving usual care for sleep. Patient participants were recruited from two types of units at BWH, oncology and medical-surgical units. With the intention of reflecting the heterogeneity of the patient population, we implemented minimal selection of participants. For the purpose of this pilot test, the inclusion criteria for patient participants were: inpatient admission at BWH, older than 18, alert and cognitively intact, and able to understand and speak English.

Study Enrollment: Newly admitted patients on the study units were reviewed with the nurses to identify the potential study participants. For potential patient participant, the patient's nurse mentioned this study to him/her and the care partner, and checked the willingness to be contacted by a member of our study team. A trained research assistant then invited the patient to participate, typically on the day of the admission. At this time, we explained the purpose, inclusion/exclusion criteria, and the procedures of the study. It was emphasized to potential patient participants that their decision to take part in the study would in no way affect

their medical treatment and clinical care at BWH. As the goal of this project is to test an innovative tool for sleep promotion, clinical care related to patient sleep may be influenced (with the purpose of sleep promotion). Written informed consent was obtained from each participant.

Randomization: After informed consent, patient was randomized into one of the two groups: 1) intervention group using the SLEEPkit, or 2) control group receiving usual care for sleep during hospitalization. A random number table offered by the project statistician guided the stratified randomization. We used a block randomization procedure where the size of blocks varied from 2 to 8. To minimize potential selection bias, the research assistants were blinded for the treatment randomization in the process of recruitment and informed consent. After the patient signed informed consent, the research assistant opened a sealed envelope with the group assignment for the specific participant ID. If the patient were randomized into the intervention group, the research assistant would download and install the SLEEPkit app on the patient personal device (smart phone or i-Pad) or the i-Pad offered by the study team. Detailed instruction was offered while the patient navigated the SLEEPkit.

Study Procedures: Table 3 summarizes the measurement, data sources, and timing of assessment for each of the study variables. All outcome variables used to evaluate the effectiveness of the SLEEPkit were collected directly from all study participants or from the medical record at baseline and at discharge. For the purpose of this project, the SLEEPkit was not linked to patient medical record, or linked to any personal identifiable data. We only recruited alert and cognitively intact patients. If one patient participant became confused or disorientated during hospitalization (e.g., the development of delirium), we stopped collecting patient self-reported outcomes, but would continue to document other pertinent outcomes.

Table 3: Outcome Measurements, Data Source, and Timing of Assessment

Study Variable		Measurement	Data Source	Timing of Assessment
Sleep and patient outcomes pertinent to sleep	Sleep quality (subjective)	PROMIS Sleep Disturbance	Patient	At admission and on the day of discharge
	Sleep quality (objective)	Actigraph (Actiwatch 2)	Patient	Continuous monitoring during hospital stay
	Sleep-related impairments	PROMIS Sleep-Related Impairment	Patient	At admission and on the day of discharge
	Common symptoms pertinent to sleep	PROMIS instruments	Patient	At admission and on the day of discharge
	Use of pharmacological sleep aid		Medical record	At discharge
	Delirium		Medical record	At discharge
	Falls		Medical record	At discharge
	Death		Medical record	At discharge
	Length of hospital stay		Medical record	At discharge

Measurements: The **Patient-Reported Outcomes Information System (**PROMIS®, www.nihpromis.org) is a National Institutes of Health-funded system of highly reliable, precise instruments of patient-reported health status for physical, mental, and social well-being. The PROMIS instruments were developed using a rigorous and systematic methodology, including a systematic process of literature reviews, expert consensus, qualitative research methods, classic test theory methods, and item response theory analyses. These methods were designed to calibrate individual items for high precision and minimal respondent biases across major symptom domains affecting health status and quality of life. The **PROMIS Sleep Disturbance** (8 questions) assesses self-reported perceptions of sleep quality, sleep depth, and restoration associated with sleep. The **PROMIS Sleep-Related Impairment** (8 questions) focuses on self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours, and the perceived functional impairments during wakefulness associated with sleep problems or impaired alertness. Other common symptoms pertinent to patient sleep will be examined by validated brief PROMIS tools, including pain (3 questions), fatigue (4 questions), anxiety (4 questions), depression (4 questions), anger (5 questions), and cognitive function (4 questions).

Sleep was also objectively measured by using **wrist actigraph** during the entire hospital stay using one of the most commonly used device, Actiwatch 2 [18]. The actigraph is a small, wrist-worn device that contains an accelerometer to monitor the number of wrist movements per epoch (e.g., 30 or 60 sec), and has been commonly used as a validated measurement for objective sleep. Sleep parameters will be derived from the Actiwatch recording by using software algorithms supplemented by the brief sleep log (patient recording of bedtime and wake time), with the primary focus on variables including total sleep time (excluding periods of wakefulness during the night), number and duration of awakenings during night, sleep efficiency (the percentage of time in bed spent sleeping).

Data Analysis: To test this hypothesis, for each subject difference scores were created by subtracting the PROMIS Sleep Disturbance score at baseline from the PROMIS score at discharge. Then regression models were fit where the primary predictor is group membership (treatment vs. control) and the response was the difference score.

4.2.2 The Feasibility of Using SLEEPkit

In addition to the evaluation of the effectiveness of the SLEEPkit, we conducted individual interviews and focus group to seek feedback from both patients and clinicians to evaluate the feasibility of using SLEEPkit in the acute care hospital setting. The interviews primarily focused on the perceived usefulness, ease of use, user control, implementation, and maintenance. We randomly selected and invited patients, family care partners, and clinicians who had experience with the SLEEPkit for the interview. For any clinicians we invited to participate to provide feedback for SLEEPkit, we emphasized that their participation in this study in voluntary and their decision whether or not to participate in the interview or surveys would not impact their work at the BWH. The PI or a trained research assistant conducted the interviews. A semi-structured interview guide was used to focus and facilitate the interview process. The interviewers maintained field notes to describe the environment and the participant(s) at the time of the interview. The interview ended whenever participants believe they had fully completed their descriptions. Each interview was 30 to 60 minutes in duration.

Data Analysis: Actual names and other personal identifying information were deleted from the audiotapes before transcription. Each interview transcript and corresponding field notes were read through several times to gain an overall orientation. Data was reorganized, reduced and categorized based on common themes; off-topic digressions were eliminated; and spoken language simplified. *Content analysis* including data reduction, data display, and conclusion-drawing was performed for each interview to derive topical codes to interpret the data. The computer software NVivo was used to manage the coding process. Based on the coding, initial categories (e.g., similar codes) and salient themes were identified.

5. Results

5.1. The Refined SLEEPkit

The final validated FAIS scale included 14 items in three subscales (Table 4).

Table 4: FAIS Items' Factor Loadings and Descriptive Characteristics

FAIS Item	Factor loading	Item total correlation	Mean (SD)
Factor 1 [4 items]: Emotional or physical impairment due to illness or hospitalization (5.4 Eigenvalues; 21% Variance) Mean (Standard Deviation): 3.5 (2.6), Median 3.1, Range 0-10, α Value 0.82			
1. Worried about medical condition or procedures	.71	.56	4.6(3.6)
2. Uninformed about nighttime care plan	.65	.64	3.2(3.0)
3. Changes to the normal bedtime routine	.78	.74	2.9(3.0)
4. Reduced daily activity	.81	.63	3.4(3.1)
Factor 2 [4 items]: Sleep disturbance due to discomfort or care plan schedule (1.4 Eigenvalues; 18.1% Variance) Mean (Standard Deviation): 4.6 (2.5), Median 5.0, Range 1-10, α Value 0.72			
5. Pain	.38	.30	4.6(3.5)
6. Awakened to take medications	.83	.65	5.5(3.5)
7. Awakened for vital signs & assessment	.88	.70	5.3(3.4)
8. Awakened for personal hygiene (e.g., bathing, changing the liens, using the bathroom)	.56	.45	2.5(3.2)
Factor 3 [6 items]: Sleep interruption due to hospital environment or medical care (1.1 Eigenvalues; 17.3% Variance) Mean (Standard Deviation): 2.7 (1.9), Median 2.5, Range 1-10, α Value 0.74			
9. Alarm noise	.84	.53	2.7(2.5)
10. Staff talking	.67	.56	2.8(2.6)
11. Excessive lighting*	.42	.53	3.7(3.4)
12. Bedding discomfort	.66	.48	2.8(2.8)
13. IV discomfort*	.48	.36	1.8(2.5)
14. Catheters or drains concerns	.35	.43	2.5(3.0)

Figure 2: Icons for Sleep-Disturbing Factors in the SLEEPkit

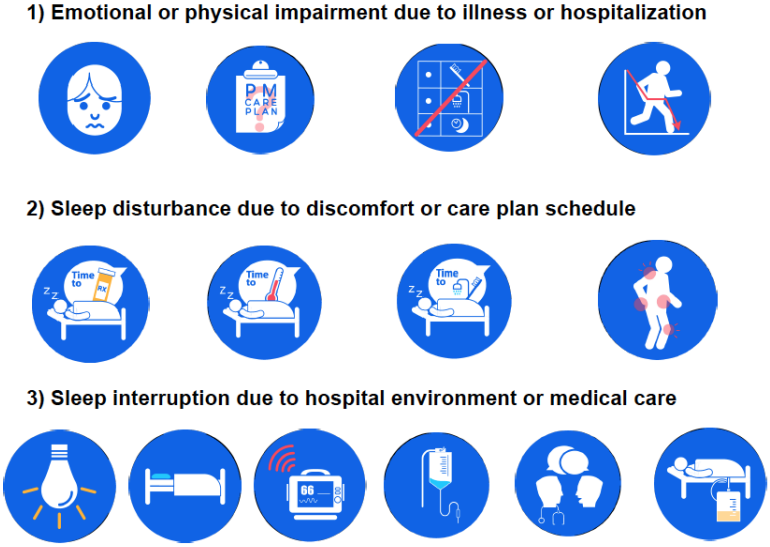
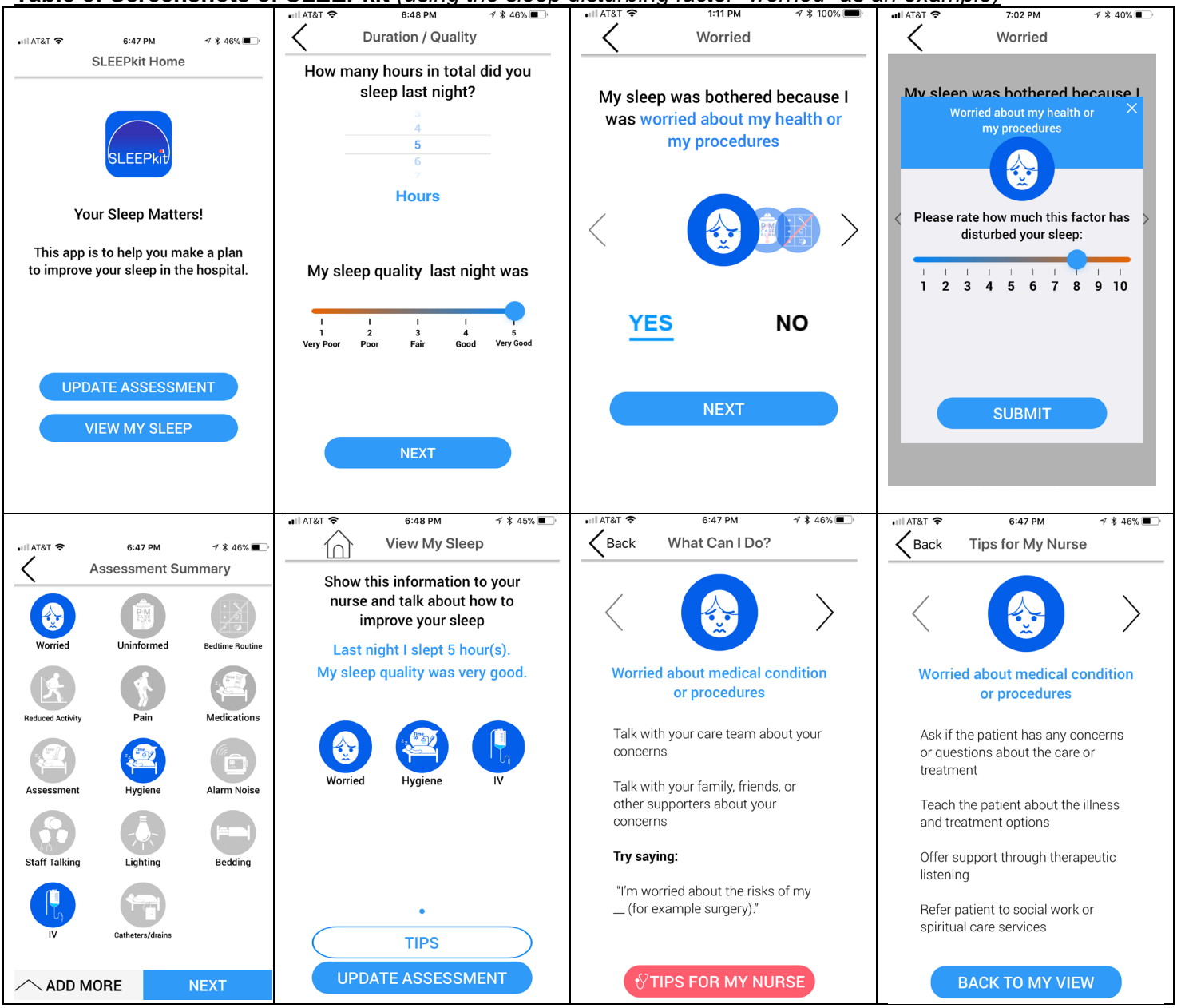


Table 5: Screenshots of SLEEPkit *(using the sleep disturbing factor "worried" as an example)*



5.2. The Effectiveness of SLEEPkit

**** As my team continues to refine the analyses of the data, the following sessions and tables report the findings from our preliminary analyses****

Table 6: Sample Characteristics

Characteristics	Total N=126	SLEEPkit Group N=65	Control Group N=61	P value
Oncology patients (%)	26.2%	29.2%	23.0%	.423
Females (%)	48.4%	46.9%	49.2%	.797
Age, years	59.5±15.0	60.6±14.2	58.4±15.8	.455
Hispanics (%)	6.3%	9.2%	3.3%	.162
Race[&], white (%)	71.4%	70.8%	72.1%	.560
Confidence of using mobile device, on a scale from 1 (least) to 10 (greatest possible)	7.4±2.7	7.8±2.3	7.1±3.0	.161
Perceived importance of sleep while in hospital, on a scale from 1 (least) to 10 (greatest possible)	8.4±1.8	8.6±1.6	8.2±2.0	.326

&: other racial groups include: American Indian/ Alaska Native (n=1, 0.8%); Asian (n=2, 1.6%); Black or African American (n=5, 4.0%); More than one race (n=2, 1.6%); Other (n=13, 10.3%); unknown/ missing (n=13, 10.3%).

No significant group differences were observed in the type of patient, sex, age, ethnicity, race, confidence of using mobile devices, or the perceived importance of sleep while in hospital. In addition, No significant group differences were observed in other demographic or clinical variables, including education, household income, employment status, marital status, co-sleep status, usual sleep duration, or the existence of a diagnosed sleep disorder.

Table 7: Group comparisons in sleep and other pertinent outcome variables

Outcomes	SLEEPkit Group			Control Group			P value (change between groups)
	Baseline	At discharge	Change	Baseline	At discharge	Change	
Sleep Disturbance	56.4±9.2	55.8±8.5	-0.1±10.3	53.5±9.6	55.8±8.7	1.1±11.3	.585
Sleep-Related Impairment	53.8±10.1	53.6±10.1	0.2±11.1	55.3±9.2	55.2±8.8	-0.7±9.2	.705
Pain	48.5±10.6	48.8±9.8	0.3±8.5	50.1±10.2	50.2±10.7	-0.2±9.5	.769
Fatigue	57.0±11.3	54.1±10.9	-2.6±12.0	56.4±9.5	54.8±10.0	-1.4±10.3	.603
Depression	51.6±10.1	50.0±8.5	-0.9±8.0	50.8±10.1	48.5±10.3	-1.5±9.2	.756
Anxiety	52.5±9.4	50.3±9.1	-1.0±10.9	51.7±10.6	49.3±10.8	-1.5±10.1	.829
Anger	49.3±11.8	45.4±10.1	-5.1±12.7	48.3±11.3	45.0±12.9	-3.7±13.7	.610
Cognitive function	45.7±10.7	48.4±10.7	1.7±9.4	46.9±10.0	50.9±10.3	4.6±11.8	.195
	Average during hospitalization			Average during hospitalization			
Total sleep time (hours:mins)	5:52±1:58			6:17±2:10			.311
Sleep onset latency	11.2±18.8			8.0±13.2			.342
Sleep efficiency	80.8±14.8			83.3±8.7			.327
Wake after sleep onset (mins)	55.6±32.0			58.8±28.1			.598
Awakenings	31.4±17.9			31.1±13.5			.931
Length of stay in hospital (days)	3.7±1.8			3.4±1.9			.332

Overall we did not observe any significant group differences in sleep and pertinent outcome variables between intervention and control groups. The PROMIS Sleep Disturbance Score, demonstrated the trend of worsening in control group but not in the SLEEPkit group, but the change score between groups did not achieve statistical significance. The PI is working on the missing data on other outcomes including inpatient pharmacological sleep aid use and delirium. Preliminary analyses on these outcomes did not show significant group differences. The PI is currently working with statistician to run additional analyses (including subgroup analyses) to achieve a better understanding of the data.

5.3. Feedback of SLEEPkit Use

We interviewed a total of 30 patients and clinicians, including 22 individual interviews and a focus group with nurses in one study unit.

We have summarized the feedback from both patients and clinicians in the domains of perceived usefulness, perceived ease of use, user control, implementation (e.g., barriers and enabling factors related to SLEEPkit use in the hospital), maintenance (e.g., strategies to sustain sleep promotion effort for hospitalized patients over time), quality of work life for clinicians (e.g., why or why not SLEEPkit can be a positive addition to be used at your unit). The PI is in the process of completing content analysis and summarizing the key findings for each domain. The following bullet points list some major findings from the preliminary analyses:

- Patients mostly perceived the SLEEPkit to be useful to improve their experience of sleep in the hospital. Patients commented that the SLEEPkit "*opened the door for conversation*"; "*made patient more aware*" of sleep, "*found it to be empowering*", "*proactive about own care*", or "*more comfortable asking*" help to improve their sleep.
- Clinicians positively embraced SLEEPkit on its functions to 1) help patient understand sleep issues; 2) help patient-clinician collaborate to make a plan for sleep; 3) empower patient to bring up concerns themselves; 4) help generate discussion about barriers to sleep; and 5) offer a visual for patients.
- Overall patients and clinicians commented the SLEEPkit was easy to use. Some expressed concerns of perceived difficulty of use for older patients and those who are too sick.
- To sustain the sleep promotion effort, some suggestions included "*Have a liason go around to all patients introducing the app and explaining reasons for hospital disturbances and all the doctors, house keeping, food services, nurses, nurse assistants that would cause disturbance"; "coordinate with PCAs"; "use paper version for people who do not have mobile devices".*
- It is necessary to tailor sleep promotion to patients who are most in need. A clinician "*prepopulated*" version of SLEEPkit can facilitate strategies tailoring to patients who are in need of sleep promotion.

5.4. Discussion, Limitation and Implication for Future Investigation

As we continue to analyze and gain more understanding of the data, we would like to discuss and the study limitation and implication for our future investigation in the following aspects. The PI will have a closer look at each aspect/question to support our continued investigation on sleep promotion in the acute care hospital setting. We believe the experience and results from this study have laid a groundwork for making inpatient sleep promotion effective and feasible, which will ultimately change current clinical practice related to patient sleep, hence leading to meaningful improvement in patient health, outcomes, quality of care, and cost.

User engagement (was the use/dose of SLEEPkit in the intervention group adequate?): Although we try to demonstrate and encourage the use of SLEEPkit for those in the intervention group, we found it challenging to achieve adequate use this tool, particularly in those who were very sick. For surgical patients, the first day after surgery the patient was under the influence of anesthesia. With a fast turn-around time, some patients may only stay in hospital for a limited time. We have collected individual patient data on the use of the SLEEPkit (data under review), but this data only reflects whenever patient hit "submit" button in the app. It is difficult to know how the patient used the SLEEPkit and engaged the bedside conversation with their care provider.

The need for a clinician interface of SLEEPkit: In our original proposal we have planned for a clinician interface along with the patient version. However, with the initial implementation of EPIC at Brigham and Women's Hospital, the integration of SLEEPkit into EPIC was not feasible. Alternatively, we added SLEEPkit as a component in a web-based patient portal at BWH (PROSPECT project). However, this web-based patient portal was only available in certain units and was not part of EPIC. The need of a clinician interface has been clearly demonstrated. We believe a clinician interface will support 1) a better engagement of clinician in sleep promotion, and 2) create possibility to tailor sleep promotion to patients who are in need (e.g., targeting patients who reported poor sleep on SLEEPkit).

RCT vs. unit-based clustered design vs. other design? Instead of a clustered design in two paired patient units as we originally proposed in the grant proposal, we chose an RCT design to randomize patients into intervention group using the SLEEPkit or control group receiving usual care of sleep. This change was based on the following considerations: 1) due to the recent unit change at BWH, it is impossible to find two comparable clinical units; 2) a traditional RCT randomizing patients can broaden the diversity of patient population by recruiting patients from different units. However, to minimize the contamination between groups and minimize the change of "usual care of patient sleep", we did not engage any unit-level strategies of sleep promotion in addition to the introduction of the SLEEPkit to clinicians. Our results of the lack of observed positive effect on patient sleep might be partly caused by the lack of unit-level of sleep promotion engagement.

6. List of Publications and Products

Manuscripts under review or to be submitted:

- Ye L, Owens, RL, Dykes P. Individualized sleep promotion in acute care hospitals: identifying factors that affect patient sleep (*under review*).
- Ye L and Dykes P. SLEEPkit: A sleep promotion toolkit for hospitalized patients. To be submitted to the Journal of Medical Internet Research

Published abstract:

- Ye L, Owens, RL, Dykes P. Individualized sleep promotion for hospitalized patients: identifying and mitigating factors that disturb sleep. Am J Respir Crit Care Med 2018;197, A2725.

Conference presentations:

- Ye L, Owens, RL, Dykes P. Individualized sleep promotion for hospitalized patients: identifying and mitigating factors that disturb sleep. Presented at the International Conference of the American Thoracic Society (ATS); Mini Symposium on May 21, 2018; San Diego, CA, USA.
- Ye L and Dykes P. A Sleep Promotion Toolkit for Hospitalized Patients. Third Annual Sleep & Symptom Research Symposium. Yale Center for Sleep Disturbance in Acute & Chronic Conditions. West Haven, CT. April 28, 2017.
- Ye L. Sleep Promotion in Acute Care Hospitals. In session Magnet Matters®: Nursing Research. 2016 Discover BWH. Brigham and Women's Hospital, Boston MA, November 10, 2016.
- Ye L. A Sleep Promotion Toolkit for Hospitalized Patients. Brigham and Women's Hospital The Center for Patient Safety Research and Practice Executive Council Meeting. November 3, 2016.

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