CLINICAL RESEARCH STUDY

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Efficacy of Sleep Tool Education During Hospitalization: A Randomized Controlled Trial

Peter M. Farrehi, MD,[a] Kristen R. Clore, OTRL,[b] J. Ryan Scott, MPH,[c] Giancarlo Vanini, MD,[c] Daniel J. Clauw, MD[a,c]

[a]Department of Internal Medicine, [b]Department of Physical Medicine and Rehabilitation, and [c]Department of Anesthesiology, University of Michigan Health Systems, Ann Arbor.

ABSTRACT

BACKGROUND: Patients are commonly provided tools in the hospital to overcome poor sleep. Whether education on use of sleep tools can impact health outcomes from a patient perspective is not known.

METHODS: We recruited 120 adults admitted to a nonintensive care unit cardiac-monitored floor. All patients received a set of sleep-enhancing tools (eye mask, ear plugs, and a white noise machine) and were randomized to receive direct education on use of and benefit of these sleep-enhancing tools (intervention), or an equal amount of time was spent discussing general benefits of sleep (control). Measurement of several symptom domains was assessed daily by health outcome survey responses, and change from baseline was assessed for differences between groups. Inpatient opioid use and length of stay were also measured.

RESULTS: Participants randomized to receive the education intervention had a significantly greater decrease in fatigue scores over the 3 days, compared with controls (5.30 ± 6.93 vs 1.81 ± 6.96, $t = 2.32$, $P = .028$). There was a trend toward improvements in multiple other sleep-related domains, including sleep disturbance, sleep-related impairment, physical functioning, pain severity, or pain interference (all $P > .140$). There was no difference in length of stay between intervention and control groups (7.40 ± 7.29 vs 7.71 ± 6.06 days, $P = .996$). The change in number of opioid equivalents taken did not differ use between the groups ($P = .688$).

CONCLUSION: In a randomized trial of education in the use of sleep-enhancing tools while hospitalized, patient fatigue was significantly improved, whereas several other patient-reported outcomes showed a trend toward improvements. Implementation of this very low-cost approach to improving sleep and well-being could substantially improve the patient care experience.

KEYWORDS: Health care survey; Patient outcome assessment; Sleep

Numerous studies demonstrate that patients experience disturbed sleep during hospitalization.[1-4] Poor sleep in the acutely ill can result from multiple factors, including reduced restorative sleep, greater awakenings, reduced total sleep time, and greater daytime sleep.[5] Factors difficult to modify that impact sleep are patient age, staff behavior, and equipment. One modifiable risk for disruptive sleep is hospital noise, which can be challenging to address.[6] Medical factors such as advanced age, comorbidities, and taking 3 or more prescription medications are more likely among the hospitalized, and are risk factors for abnormal sleep physiology.[7] Sleep disorders are linked with an increased risk of cardiovascular disease,[8-10] and poor sleep has been associated with increased all-cause mortality among community-dwelling populations.[11,12] In addition to therapeutic interventions, an aim of hospitals is to provide individuals comfort regarding their illness. Patients—especially the critically ill—commonly report negative experiences during hospitalization as a consequence of poor sleep.[4,13,14] Improving patient-related sleep quality is a growing quality metric in hospitals participating in value-based purchasing.[15,16]

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Requests for reprints should be addressed to Peter M. Farrehi, MD, University of Michigan Health System, Room 2722, Box 5853, 1500 E. Medical Center Drive, Ann Arbor, MI 48109.

E-mail address: pfarrehi@umich.edu

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Although there have been several studies of sleep-promoting strategies in hospitalized patients, nearly all have been conducted in the intensive care unit (ICU) setting.[4,7,13] Focus in these ICU studies has been predominantly on pharmacologic and ventilator-assisted interventions. However, most patients spend the majority of their hospital stay outside the ICU. Studies are needed about sleep-promoting education strategies among the hospitalized in non-ICU settings where hospitals could most impact patient sleep.

We performed a double-blinded randomized controlled trial to determine whether a simple education intervention would improve patients' perception about sleep quality, sleep-related impairment, fatigue, physical function, and pain in the hospital. We hypothesized that active education intervention about the use of sleep-enhancing tools, for example, earplugs, will have greater improvement in patient-reported outcome measures compared with those receiving a control. The control group also received identical sleep-enhancing tools, but was given education lasting the same length of time on the general benefits of sleep—rather than on specific use of the tools.

CLINICAL SIGNIFICANCE

- In a randomized controlled trial, education on using sleep-enhancing tools significantly improved fatigue scores in hospitalized patients and led to nonsignificant trends in improvement in multiple other related symptom domains.
- Patient education on improving hospital sleep is a simple intervention to improve patient care experience.

METHODS

Study Design and Setting

This was a single-center prospective, double-blind, randomized clinical trial undertaken from January 2014 to September 2015. The study team member obtaining consent was unblinded and did not have contact with the enrollee for the remainder of the study. The patient and all other study team members were blinded to the randomization. The study was designed to assess the impact of a patient education intervention using sleep-enhancing tools on patient-reported outcomes. All patients provided written informed consent. This trial was approved by the University of Michigan Institutional Review Board and was registered on the National Clinical Trials database (NCT02068703). The University Hospital discharged over 50,000 patients last fiscal year.

Selection of Participants

Adults aged 18-75 years who were admitted to a non-ICU monitored cardiac unit who were anticipated to have a length of stay of 4 or more days were recruited on hospital day 2. The first day served as an acclimatization period, and patients were enrolled on hospital day 2. Eligible participants were required to have an estimated length of hospital stay >4 days to ensure that adequate follow-up data were available. Reasons for exclusion included wearing hearing aids, being bedridden, receiving treatments for high-acuity medical conditions, or judgment of research team based on unstable medical illness. Clinical factors contributing to high acuity included low blood pressure, multiple intravenous medications that might require night-time adjustments, and recent transfers from ICU stay leaving the patient debilitated.

Randomization and Measurements

Following consent, an unblinded member of the research team randomly assigned patients (2:1) to the intervention or control group, through the use of a computer-generated 2, 4-variable block randomization list. The a priori sample size was based on previous trials examining the effect of an intervention program in chronic pain.[17] One hundred twenty participants with a 2:1 allocation ratio yielded 80% power to detect a 10% difference with $\alpha = 0.05$ (independent samples Student's t test). Each patient was supplied with 3 sleep-enhancing tools: 1) sleep mask (Centurion Medical, Williamston, Mich.); 2) ear plugs (3M TaperFit2, St. Paul, Minn.); and 3) white noise machine (Homedics, Commerce Township, Mich.). Patients were able to choose which aid they used, to change aids during their hospital stay, and could use one or more at any time or not use aids at all. Patients received similar contact time with study staff, regardless of group allocation, lasting approximately 10 minutes (see Appendixes A and B, available online). Both groups were read scripted discussions by the study staff on the importance of sleep and good health. Included in the intervention script, patients were given active instruction on tool use and encouraged to utilize the tools. Immediately following randomization, patients completed baseline surveys. On subsequent hospital days, a blinded study team member collected survey responses to the Patient-Reported Outcomes Information System (PROMIS; Short Form) and Brief Pain Inventory[18] (BPI) survey measurements as well as documenting self-reported use of sleep tools.

Baseline PROMIS surveys were obtained at randomization.[19] Each Short Form represents a specific domain (sleep disturbance, wake disturbance, fatigue, and physical functioning) and includes 8-10 questions with 5-point Likert-style response scale (Never, Rarely, Sometimes, Often, Always).[20] Patients were asked in the survey battery and verified by medical record to report use of opioid-derived pain and sleep-enhancing medication use.

Outcomes and Analysis

The primary outcome was not a composite but an improvement in sleep, pain, and fatigue—based on the specific domain PROMIS survey responses—over 3 days in the intervention group compared with controls. The