LAMPIRAN

Lampiran 1

Critical Appraisal for Randomized Controlled Trials (RCT)

Reviewer : Dini Indriyani Tanggal : 30 April 2021
Penulis : Mutarobin et al., Tahun : 2019 No.Literature : 1

No	Pertanyaan	Jawaban			
		Ya	Tidak	Tidak Jelas	Tidak Ada
1	Apakah penentuan kelompok dan responden penelitian dilakukan secara acak?	✓			
2	Apakah intervensi dilakukan secara tersembunyi (Blind)?	✓			
3	Apakah intervensi dilakukan sesuai standar?	✓			
4	Apakah responden dilakukan blind (tidak tahu) terhadap intervensi yang diberikan?	✓			
5	Apakah pemberi intervensi blind terhadap tindakan yang dilakukan?		✓		
6	Apakah peneliti blind terhadap intervensi yang dilakukan?		✓		
7	Apakah kelompok intervensi mendapat perlakuan yang sama dengan kelompok kontrol?	✓			
8	Ketika follow up dilakukan secara menyeluruh atau tidak, apakah tindakan selanjutnya dianalisis secara memadai?	✓			
9	Apakah responden dianalisis berdasarkan metode acak?	✓			
10	Apakah pengukuran dilakukan dengan cara yang sama pada kedua kelompok?	✓			
11	Apakah pengukuran hasil dilakukan dengan cara yang memadai atau sesuai?	✓			
12	Apakah dijelaskan uji statistic yang digunakan dan sesuai?	✓			
13	Apakah desain uji coba sesuai dengan standar RCT?	✓			

Reviewer : Dini Indriyani Tanggal : 30 April 2021
Penulis : Bajwa et al., Tahun : 2019 No.Literature : 2

No	Pertanyaan	Jawaban			
		Ya	Tidak	Tidak Jelas	Tidak Ada
1	Apakah penentuan kelompok dan responden penelitian dilakukan secara acak?	✓			
2	Apakah intervensi dilakukan secara tersembunyi (Blind)?	✓			
3	Apakah intervensi dilakukan sesuai standar?	✓			
4	Apakah responden dilakukan blind (tidak tahu) terhadap intervensi yang diberikan?	✓			
5	Apakah pemberi intervensi blind terhadap tindakan yang dilakukan?		✓		
6	Apakah peneliti blind terhadap intervensi yang dilakukan?		✓		
7	Apakah kelompok intervensi mendapat perlakuan yang sama dengan kelompok kontrol?		✓		
8	Ketika follow up dilakukan secara menyeluruh atau tidak, apakah tindakan selanjutnya dianalisis secara memadai?	✓			
9	Apakah responden dianalisis berdasarkan metode acak?	✓			
10	Apakah pengukuran dilakukan dengan cara yang sama pada kedua kelompok?	✓			
11	Apakah pengukuran hasil dilakukan dengan cara yang memadai atau sesuai?	✓			
12	Apakah dijelaskan uji statistic yang digunakan dan sesuai?	✓			
13	Apakah desain uji coba sesuai dengan standar RCT?	✓			

Reviewer : Dini Indriyani Tanggal : 1 Mei 2021
Penulis : Arttawejkul et al., Tahun : 2020 No.Literature : 3

No	Pertanyaan	Jawaban			
		Ya	Tidak	Tidak Jelas	Tidak Ada
1	Apakah penentuan kelompok dan responden penelitian dilakukan secara acak?	✓			
2	Apakah intervensi dilakukan secara tersembunyi (Blind)?	✓			
3	Apakah intervensi dilakukan sesuai standar?	✓			
4	Apakah responden dilakukan blind (tidak tahu) terhadap intervensi yang diberikan?		✓		
5	Apakah pemberi intervensi blind terhadap tindakan yang dilakukan?	✓			
6	Apakah peneliti blind terhadap intervensi yang dilakukan?	✓			
7	Apakah kelompok intervensi mendapat perlakuan yang sama dengan kelompok kontrol?		✓		
8	Ketika follow up dilakukan secara menyeluruh atau tidak, apakah tindakan selanjutnya dianalisis secara memadai?	✓			
9	Apakah responden dianalisis berdasarkan metode acak?	✓			
10	Apakah pengukuran dilakukan dengan cara yang sama pada kedua kelompok?	✓			
11	Apakah pengukuran hasil dilakukan dengan cara yang memadai atau sesuai?	✓			
12	Apakah dijelaskan uji statistic yang digunakan dan sesuai?	✓			
13	Apakah desain uji coba sesuai dengan standar RCT?	✓			

Reviewer : Dini Indriyani Tanggal : 1 Mei 2021
Penulis : Demoule et al., Tahun : 2020 No.Literature : 4

No	Pertanyaan	Jawaban			
		Ya	Tidak	Tidak Jelas	Tidak Ada
1	Apakah penentuan kelompok dan responden penelitian dilakukan secara acak?	✓			
2	Apakah intervensi dilakukan secara tersembunyi (Blind)?	✓			
3	Apakah intervensi dilakukan sesuai standar?	✓			
4	Apakah responden dilakukan blind (tidak tahu) terhadap intervensi yang diberikan?	✓			
5	Apakah pemberi intervensi blind terhadap tindakan yang dilakukan?		✓		
6	Apakah peneliti blind terhadap intervensi yang dilakukan?		✓		
7	Apakah kelompok intervensi mendapat perlakuan yang sama dengan kelompok kontrol?		✓		
8	Ketika follow up dilakukan secara menyeluruh atau tidak, apakah tindakan selanjutnya dianalisis secara memadai?	✓			
9	Apakah responden dianalisis berdasarkan metode acak?	✓			
10	Apakah pengukuran dilakukan dengan cara yang sama pada kedua kelompok?	✓			
11	Apakah pengukuran hasil dilakukan dengan cara yang memadai atau sesuai?	✓			
12	Apakah dijelaskan uji 80egative80 yang digunakan dan sesuai?	✓			
13	Apakah desain uji coba sesuai dengan standar RCT?	✓			

Reviewer : Dini Indriyani Tanggal : 2 Mei 2021
Penulis : Dave et al., Tahun : 2013 No.Literature : 5

No	Pertanyaan	Jawaban			
		Ya	Tidak	Tidak Jelas	Tidak Ada
1	Apakah penentuan kelompok dan responden penelitian dilakukan secara acak?	✓			
2	Apakah intervensi dilakukan secara tersembunyi (Blind)?				
3	Apakah intervensi dilakukan sesuai standar?	✓			
4	Apakah responden dilakukan blind (tidak tahu) terhadap intervensi yang diberikan?	✓			
5	Apakah pemberi intervensi blind terhadap tindakan yang dilakukan?		✓		
6	Apakah peneliti blind terhadap intervensi yang dilakukan?		✓		
7	Apakah kelompok intervensi mendapat perlakuan yang sama dengan kelompok kontrol?	✓			
8	Ketika follow up dilakukan secara menyeluruh atau tidak, apakah tindakan selanjutnya dianalisis secara memadai?	✓			
9	Apakah responden dianalisis berdasarkan metode acak?	✓			
10	Apakah pengukuran dilakukan dengan cara yang sama pada kedua kelompok?	✓			
11	Apakah pengukuran hasil dilakukan dengan cara yang memadai atau sesuai?	✓			
12	Apakah dijelaskan uji 81egative81 yang digunakan dan sesuai?	✓			
13	Apakah desain uji coba sesuai dengan standar RCT?	✓			

Critical Appraisal for Quasi Experimental Studies (non randomized)

Reviewer : Dini Indriyani Tanggal : 2 Mei 2021
Penulis : Bani Younis et al., Tahun : 2018 No.Literature : 6

No	Pertanyaan	Jawaban			
		Ya	Tidak	Tidak Jelas	Tidak Ada
1	Apakah cukup jelas sebab dan akibat dari variabel yang akan diteliti?	✓			
2	Apakah responden termasuk dalam perbandingan yang sama?	✓			
3	Apakah responden mendapatkan intervensi pada setiap kelompok?		✓		
4	Apakah terdapat kelompok kontrol?	✓			
5	Apakah terdapat penilaian hasil dari sebelum dan sesudah intervensi?	✓			
6	Ketika follow up dilakukan secara menyeluruh atau tidak, apakah tindakan selanjutnya dianalisis secara memadai ?	✓			
7	Apakah pengukuran antara dua kelompok dilakukan dengan cara yang sama?	✓			
8	Apakah pengukuran hasil dilakukan dengan cara yang memadai/sesuai?	✓			
9	Apakah dijelaskan uji 82egative82 yang digunakan dan sesuai?	✓			

Lampiran 2

ConQual Summary of Fidings

Jurnal 1					
Judul : Penerapan *Evidence Based Nursing* Pengaruh *Earplug* dan *Eye Mask* Terhadap Kualitas Tidur pada Pasien di ICU **Subjek Penelitian :** 24 pasien di ruang ICU Rumah Sakit Jantung dan Pembuluh Darah Harapan Kita ***Phenomena of Interest* :** Pasien yang dirawat di ruang ICU mengalami perubahan dalam tidurnya. Pasien mengalami jam tidur yang singkat dan kesulitan dalam mencapai tidur REM sehingga menyebabakan pasien menjadi mudah terbangun.					
Synthesized finding	*Type of research*	*Dependability*	*Credibility*	*ConQual Score*	*Comments*
Earplug dan *eye mask* merupakan intervensi yang dapat meningkatkan kualitas tidur, dan dapat digunakan sebagai alternatif pengganti obat tidur untuk pasien di ruang ICU yang mengalami kesulitan mengawali proses tidur.	Kuantitatif (RCT)	*The paper remains unchanged* (Layak)	Seluruh pertanyaan : *Yes* 11 *No* 2	*High* (Tinggi)	*Grade* rekomendasi berdasarkan FAME termasuk kategori A, temuan tegas atau tidak berubah**.**

Jurnal 2

Judul : *Effect of Ear Plugs & Eye Mask On Sleep Among ICU Patients: A Randomized Control Trial*

Subjek Penelitian : 100 pasien di ruang ICU DMC & Hospital, Ludhiana

***Phenomena of Interest* :** Pasien di ruang ICU memiliki kualitas tidur yang buruk, berkaitan dengan ritme sikardian dan siklus tidur yang tidak teratur serta penurunan waktu total tidur yang jika dibiarkan dapat memperburuk kondisi pasien.

Synthesized finding	*Type of research*	*Dependability*	*Credibility*	*ConQual Score*	*Comments*
Penggunaan *earplug* dan *eye mask* menunjukan efek yang signifikan dalam meningkatkan kualitas tidur dan dianggap sebagai metode yang efektif , sederhana, dan hemat biaya yang dapat memperbaiki pola tidur pasien yang dirawat di ruang ICU.	Kuantitatif (RCT)	*The paper remains unchanged* (Layak)	Seluruh pertanyaan : *Yes* 10 *No* 3	*High* (Tinggi)	*Grade* rekomendasi berdasarkan FAME termasuk kategori A, temuan tegas atau tidak berubah**.**

Jurnal 3

Judul : *Effect of Nighttime Earplugs and Eye Masks on Sleep Quality in Intensive Care Units Patients*

Subjek Penelitian : 17 pasien di ruang ICU

Phenomena of Interest : Kualitas tidur yang buruk dpat menurunkan daya tahan otot dan menyebabkan weaning ventilasi mekanik yang lebih lama. Selain kualitas yang buruk, derilium juga sering ditemukan pada pasien di ruang ICU.

Synthesized finding	Type of research	Dependability	Credibility	ConQual Score	Comments
Penggunaan *earplug* dan *eye mask* tidak secara signifikan dapat meningkatkan kualitas tidur. Hasil tersebut disebabkan karena ukuran sampel yang terbatas sehingga tidak terlihat perbedaan yang signifikan antara kelompok intervensi dan kelompok kontrol.	Kuantitatif (RCT)	*The paper remains unchanged* (Layak)	Seluruh pertanyaan: *Yes* 11 *No* 2	*High* (Tinggi)	*Grade* rekomendasi berdasarkan FAME termasuk kategori A, temuan tegas atau tidak berubah**.**

Jurnal 4					
Judul : *Impact of Earplugs and Eye Mask on Sleep in Critically Ill Patients : A Prospective Randomized Study* **Subjek Penelitian :** 64 pasien di ruang ICU ***Phenomena of Interest* :** Tidur yang buruk sering terjadi pada pasien yang di ruang ICU, yang disebabkan oleh faktor lingkungan khususnya kebisingan dn pencahayaan.					
Synthesized finding	*Type of research*	*Dependability*	*Credibility*	*ConQual Score*	*Comments*
Penggunaan *earplug* dan *eye mask* pada pasien di ruang ICU ketika malam hari dpat meingkatkan durasi tidur NREM III, menurunkan frekuensi terbangun dari tidur. *Earplug* dan *eye mask* merupakan intervensi yang dapat ditoleransi oleh tubuh dengan baik.	Kuantitatif (RCT)	*The paper remains unchanged* (Layak)	Seluruh pertanyaan: *Yes* 10 *No* 3	*High* (Tinggi)	*Grade* rekomendasi berdasarkan FAME termasuk kategori A, temuan tegas atau tidak berubah**.**

Jurnal 5

Judul : *Effects of Earplugs and Eye Masks on Perceived Quality of Sleep During Night Among Patients in Intensive Care Units*

Subjek Penelitian : 50 pasien di ruang ICU

Phenomena of Interest **:** Gangguan tidur merupakan masalah umum yang terjadi pada pasien di ruang ICU yang disebabkan oleh banyak faktor. Kebisingan dan pencahayaan adalah faktor paling umum yang berpengaruh pada fisiologis dan psikologis 87egative pada pasien yang dirawat di ruang ICU.

Synthesized finding	*Type of research*	*Dependability*	*Credibility*	*ConQual Score*	*Comments*
Earplug dan *eye mask* merupakan intervensi sederhana untuk meningkatkan kualitas tidur pasien di ruang ICU. Intervensi ini dapat diterima dengan baik dapat menjadi alternatif pengganti obat tidur ssesuai dengan kondisi pasien.	Kuantitatif (RCT)	*The paper remains unchanged* (Layak)	Seluruh pertanyaan: *Yes* 11 *No* 2	*High* (Tinggi)	*Grade* rekomendasi berdasarkan FAME termasuk kategori A, temuan tegas atau tidak berubah**.**

Jurnal 6

Judul : *Effectiveness of Using Eye Mask and Earplugs on Sleep Length and Quality Among Inntensive Care Patients: A Quasi Experimental Study*

Subjek Penelitian : 103 pasien di ruang ICU

***Phenomena of Interest* :** Kualitas tidur yang buruk sering terjadi pada pasien di ruang ICU, dimana pasien memiliki rentang waktu tidur normal namun pasien tersebut mengalami penurunan *sleep slow waves* dan ridur REM.

Synthesized finding	*Type of research*	*Dependability*	*Credibility*	*ConQual Score*	*Comments*
Ketika pasien menggunakan *eye mask* dapat membuat suasana ruangan menjadi gelap yang menyebabkan otak menganggap suasana gelap ini sebagai waktu malam dan mengirimkan stimulus pada kelenjar pineal untuk meningkatkan sekresi hormon melatonin. Sedangkan *earplug* dapat menurunkan kebisingan yang dasakan oleh pasien sebesar 32 dB sehingga menyebabkan	Kuantitatif (Quasi eksperimen)	*The paper remains unchanged* (Layak)	Seluruh pertanyaan: *Yes* 8 *No* 1	*High* (Tinggi)	*Grade* rekomendasi berdasarkan FAME termasuk kategori A, temuan tegas atau tidak berubah**.**

penurunan rasa terjaga ketikan pasien memulai tidur.					

Lampiran 3

CATATAN BIMBINGAN SKRIPSI

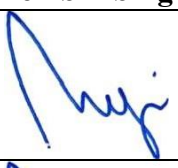
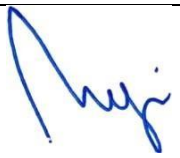
Nama Mahasiswa **:Dini Indriyani**

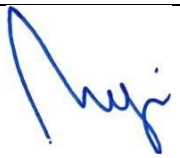
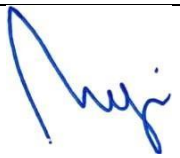
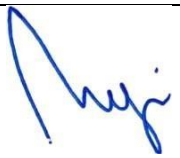
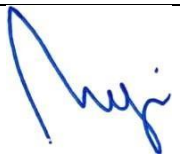
NIM **:AK117161**

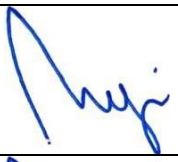
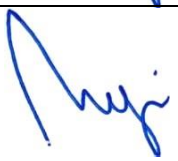
Judul Skripsi **:Pengaruh Penggunaan *Earplug* dan *Eye Mask* Terhadap Kualitas Tidur pada Pasien di Ruang ICU : Literature Review**

Pembimbing Utama **:Sri Wulan Megawati, S.Kep., Ners.,M.Kep**

Pembimbing Pendamping **:Titin Mulyati, S.Kp., M.Kep**

No	Hari/Tanggal	Catatan Pembimbing	Paraf Pembimbing
1.	Minggu 27 Desember 2020	ACC Judul	
2.	Rabu 6 Januari 2021	BAB I Sistematika Paragraf Definisi ICU – Kondisi ruangan ICU yang dapat mempengaruhi kualitas tidur – Definisi tidur – Cara meningkatkan kualitas tidur – Pilihan intervensi untuk meningkatkan kualitas tidrur – *Earplug* dan *Eye Mask* – Kelebihan *earplug* dan *eye mask* – hasil penelitian.	
3.	Senin 11 Januari 2021	BAB I 1. Pembahasan mengenai kriteria pasien masuk ke ruang ICU dijelaskan garis besarnya saja. 2. Perbaiki sistematika paragraf BAB II sudah bisa mulai dikerjakan.	

4.	Minggu 31 Januari 2021	BAB I ACC BAB II 1. Untuk keseluruhan cek margin dan spasi 2. Perbaiki penomoran 3. Tambahan penjelasan pada intervensi famakologis dan non farmakologis untuk meningkatkan kualitas tidur 4. Tambahkan sumber literature pada penjelasan mengenai efektifitas penggunaan *earplug* dan *eye mask* terhadap kualitas tidur pada pasien di ruang ICU	
5.	Minggu 7 Februari 2021	BAB I ACC BAB II Tambahkan hasil penelitian pada penjelasan mengenai pengaruh *earplug* dan *eye mask*. BAB III sudah bisa mulai dikerjakan.	
6.	Sabtu 13 Februari 2021	BAB I ACC BAB II ACC BAB III 1. Jumlah populasi jangan dulu dimunculkan 2. Cari desai penelitian lain selain RCT 3. Kembangkan sumber data base 4. Pengkategorian jurnal di JBI menurut kelas dan klasifikasinya BAB IV bisa mulai dikerjakan	
7.	Selasa 23 Februari 2021	BAB I ACC BAB II ACC BAB III 1. Perjelas indeks jurna resmi seperti apa kategorinya (ISSN, eISSN, DOI)	

		BAB IV Untuk sementara cukup, konsultasikan dengan pembimbing 2.	
8	Rabu 3 Maret 2021	Hasil plagiat 14%, sambil konsultasikan dengan pembimbing 2 jika sudah selesai lanjut untuk UP.	
9	Selasa 16 Maret 2021	**ACC UP**	
10	Minggu 11 April 2021	Revisi Proposal Penelitian BAB I - BAB II Tambahkan tentang kebutuhan tidur pasien ICU BAB III - BAB IV -	
11	Rabu 21 April 2021	Lanjutkan ke BAB Selanjutnya, minta ACC penguji.	
12	Selasa 25 Mei 2021	BAB V Untuk pembahasan kaitkan dengan teori yang sudah ada.	
13	Rabu 2 Juni 2021	**-ACC Sidang Akhir** -Lanjutkan dulu dengan pembimbing 2	
14	Selasa 15 Juni 2021	Abstrak 1. Perhatikan kaidah IMRAD, lihat panduan BAB I - BAB II - BAB III 1. Hilangkan bahasa proposal BAB IV 1. Boolenas operators	

		sesuaikan dengan yang digunakan BAB V 1. Pada tabel 5.1 jelaskan populasi dan sampel, hasil dibuat poin 2. Pembahasan kaitkan dengan teori	
15	Senin 28 Juni 2021	**ACC Sidang Akhir**	
16	Rabu 21 Juli 2021	**ACC revisi sidang akhir**	
17	Senin 9 Agustus 2021	**ACC Manuskrip**	
18	Minggu 15 Agustus 2021	**ACC Poster**	

CATATAN BIMBINGAN SKRIPSI

Nama Mahasiswa **:Dini Indriyani**

NIM **:AK117161**

Judul Skripsi **:Pengaruh Penggunaan *Earplug* dan *Eye Mask* Terhadap Kualitas Tidur pada Pasien di Ruang ICU : Literature Review**

Pembimbing Utama **:Sri Wulan Megawati, S.Kep., Ners.,M.Kep**

Pembimbing Pendamping **:Titin Mulyati, S.Kp., M.Kep**

No	Hari/Tanggal	Catatan Pembimbing	Paraf Pembimbing
1.	Senin 28 Desember 2020	ACC Judul	
2.	Minggu 10 Januari 2021	BAB I 1. Tambahkan penjelasan tentang kriteria pasien yang dirawata di ruang ICU sehingga memerlukan support alat, agar masuk ke penjelasan kebisingan pada paragraf berikutnya. 2. Tambahkan tentang bioritmik (perubahan pola tidur pasien diruang ICU) 3. Perbaiki cara penulisan citasi 4. *Earplug* dan *eye mask* dibuta penjelasan pada paragraf yang berbeda, kemudian buat paragraf gabungan 5. Perjelas intervesi pada hasil penelitian, apakah	

		earplug atau *eye mask* saja atau gabungan dari keduanya 6. Uraikan hasil penelitian 7. Pada manfaat teoritis (Bagi Institusi) kalimat "…bagi dosen dan masiswa" ganti menjadi "…dan menambah wawasan dalam ilmu keperawatan" 8. Pada manfaat praktis (bagi rumah sakit) kalimat "…kebijakan kepada rumah sakit" ganti menjadi "…Standar Prosedur Operasional (SPO) di rumah sakit".	
3	Kamis 14 Januari 2021	BAB I ACC Lantutkan ke BAB II	
4	Jumat 13 Februari 2021	BAB I 1. Tambahkan penjelasan untuk pasien dengan tingkat kesadaran seperti apa yang bisa diberikan intervensi *earplug* dan *eye mask* 2. Tambahakan penjelasan perbedaan tingkat kebisingan antara siang dan malam terhadap bioritmik pasien 3. Tambahkan penjelasan rekomeendasi tingkat pencahayaan di ruang ICU 4. Ganti kata "efektivitas" menjadi "pengaruh" BAB II 1. Cari paradigma keperawatan tentang kualitas tidur 2. Kerangka konseptual	

		dimulai dari pasien kritis-gangguan tidur-kualitas tidur-dampak gangguan tidur-penatalaksanaan-farmakologis dan non farmakologis. Lanjutkan BAB III, lengkapi draft.	
5	Jumat 26 Februari 2021	BAB I 1. Lengkapi tahun pada sumber WHO 2. Sedikit perbaikan pada manfaat bagi peneliti selanjutnya BAB II 1. Penomoran dan Spasi 2. Perbaiki tabel 2.1 BAB III - BAB IV - DAFTAR PUSTAKA Perbaiki cara penulisan	
6	Sabtu 13 Maret 2021	**ACC UP**, dengan sedikit perbaikan. COVER 1. Spasi BAB I 1. Tambahkan lagi tentang kondis pasien yang di rawat di ruang ICU BAB II 1. Ganti kata "disfungsi" menjadi "gamgguan" 2. Buat sub judul baru tentang kondisi pasien kritis – pemantauan ketat – gangguan tidur BAB III 1. Pada etika penelitian ganti kata "tidak" menjadi "tidak akan" karena baru proposal	

		BAB IV 1. Penomoran	
7	Rabu 14 April 2021	Lanjutkan ke BAB selanjutnya.	
8	Senin 26 April 2021	1. Lanjutkan ke BAB selanjutnya 2. Cek penulisan bahasa asing 3. BAB III da IV jangan bahasa proposal	
9	Sabtu 5 Juni 2021	BAB I 1. Perbaiki spasi 2. Konfirmasi ke dosen akademik mengenai tujuan khusus BAB II 1. Lihat panduan mengenai ukuran huruf dalam tabel 2. Sumber dibawah tabel tidak usah di bold BAB III 1. Hilangkan poin 2 di kriteria eksklusi BAB IV 1. Perbaiki penulisan bahsa asing 2. Ukuran huruf pada tabel, tebel terbuka 3. Ganti kata “jika, apabila” 4. Tambahkan Booleans operator dalam bahasa Indonesia BAB V 1. Pada paragraf baru tidak menggunakan kata sambung 2. Cek hasil jurnal 3. Cari sumber terbaru BAB VI	

		1. Perbaiki simpulan dan saran	
10	Selasa 15 Juni 2021	Abstrak 1. Tambahkan p-*value* pada hasil penelitian dari setiap artikel 2. Tambahkan pembahasan sebelum dan sesudah intervesi BAB I 1. Perbaiki tujuan khusus BAB II - BAB III - BAB IV 1. Tambahkan *booleans operators* untuk pencarian yang menggunakan bahasa Indonesia BAB V 1. Tambahkan pembahasan mengenai sebelum dan sesudah intervensi BAB VI 1. Perbaiki simpulan **ACC SIDANG AKHIR (** dengan perbaikan)	
11	Senin 21 Juni 2021	**ACC SIDANG AKHIR**	
12	Rabu 28 Juli 2021	**REVISI DRAFT SIDANG AKHIR** - Daftar singkatan berurutan sesuai abjad - Perbaiki spasi pada tabel 5.1 dan daftar pustaka	
13	Selasa 17 Agustus 2021	**ACC Manuskrip**	

Lampiran 4

MATRIKS EVALUASI SKRIPSI
PROGRAM STUDI SARJANA KEPERAWATAN
TAHUN AKADEMIK 2020/2021

Nama Mahasiswa : DINI INDRIYANI

NIM : AK117161

Pembimbing : 1. Sri Wulan Megawati, S.Kep., Ners., M.Kep

2. Titin Mulyati, S.Kp., M.Kep

Penguji : **R. Siti Jundiah, S.Kp., M.Kep**

No	Perbaikan / Masukan (diisi pada saat ujian oleh Penguji)	Hasil Revisi (diisi oleh Mahasiswa sebagai bentuk jawaban perbaikan/masukan Penguji)
1	BAB I - Untuk litrev pada tahap pengajuan proposal penelitian, tujuan khusus dihilangkan, ada atau tidaknya tujuan khusus nanti mengikuti pembahasan hasil penelitian. - Perbaiki manfaat teoritis (bagi ilmu keperawatan) dan manfaat praktis (bagi rumah sakit) mengenai "EBP" dan "SOP" apakah sama atau berbeda?	Sudah diperbaiki sesuai saran.
2	BAB II - Pada dampak gangguan tidur tambahkan tanda dan gejalanya, tambahkan juga	Materi mengenai dampak gangguan tidur, serta tanda dan gejalanya sudah ditambahkan.

	pada fenomena di BAB I.	
3	BAB III -	
4	BAB IV -	
5	ABSTRAK Tambahkan dampak gangguan tidur pada pasien ICU BAB IV Tambahkan penjabaran mengenai kerangka FAME dan *ConQual summary of findings*	Sudah diperbaiki sesuai saran.

Mengetahui,

Sebelum Revisi	Setelah Revisi
1. Mahasiswa : 2. Pembimbing : 3. Penguji :	1. Mahasiswa : 2. Pembimbing : 3. Penguji :

MATRIKS EVALUASI SKRIPSI
PROGRAM STUDI SARJANA KEPERAWATAN
TAHUN AKADEMIK 2019/2020

Nama Mahasiswa : DINI INDRIYANI

NIM : AK117161

Pembimbing : 1. Sri Wulan Megawati, S.Kep., Ners., M.Kep

2. Titin Mulyati, S.Kp., M.Kep

Penguji : **Denni Fransiska H.M., S.Kp., M.Kep**

No	Perbaikan / Masukan (diisi pada saat ujian oleh Penguji)	Hasil Revisi (diisi oleh Mahasiswa sebagai bentuk jawaban perbaikan/masukan Penguji)
1	BAB I - Cek typo - Pada hal.5 setiap kalimat atau paragraf harus ada kesinambungan kata	Sudah diperbaiki sesuai saran.
2	BAB II - Tambahkan kajian pustaka - Hilangkan teori model keperawatan - Tambahkan judul pada bagan 2.1	- Kajian pustaka sudah ditambahkan - Teori Model Keperawatan sudah dihilangkan - Judul pada bagan 2.1 sudah ditambahkan
3	BAB III -	
4	BAB IV - Tambahkan "*comparison*" pada metode PICOD	Sudah ditambahkan.
5	DAFTAR PUSTAKA	Sudah diperbaiki.

	Perbaiki, masih ada yang kurang tepat.	
6	BAB I Hilangkan tujuan khusus sehingga pada BAB V Pembahasan sesuaikan dengan hasil temuan. BAB IV Kaji ulang PICOD, terutama pada bagian *Comparison*.	

Mengetahui,

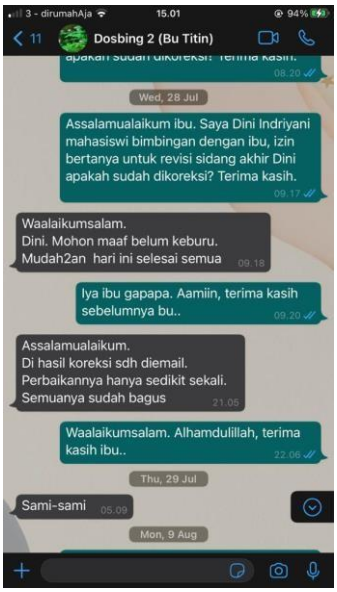
Sebelum Revisi	Setelah Revisi
1. Mahasiswa : 2. Pembimbing : 3. Penguji :	1. Mahasiswa : 2. Pembimbing : 3. Penguji :

Lampiran 5

BUKTI ACC PEMBIMBING PASCA SIDANG AKHIR

Pembimbing 1: Sri Wulan Megawati, S.Kep., Ners., M.Kep

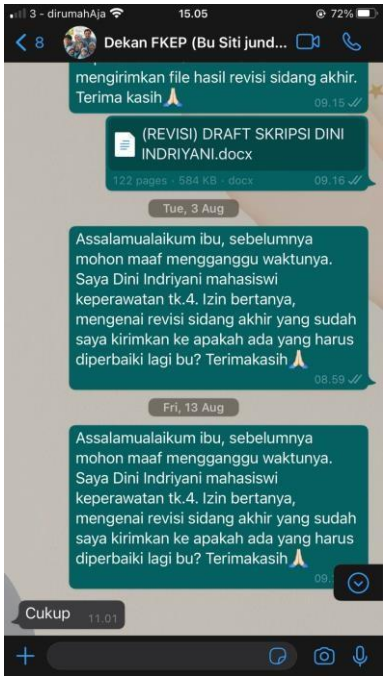
Pembimbing 2 : Titin Mulyati, S.Kp., M.Kep



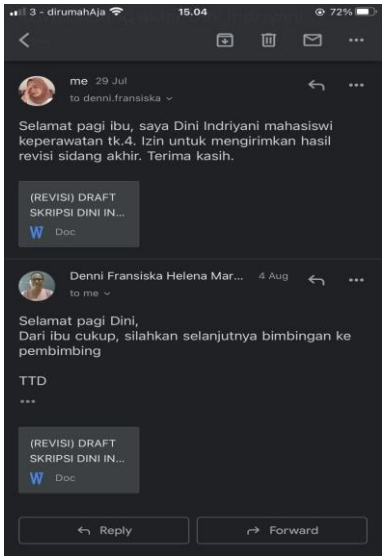
Lampiran 6

BUKTI ACC PENGUJI PASCA SIDANG AKHIR

Penguji 1 : R. Siti Jundiah, S.Kp., M.Kep



Penguji 2 : Denni Fransiska H.M., S.Kp., M.Kep



Lampiran 7

BUKTI MENJADI OPONEN

Nama : Dini Indriyani

NIM : AK117161

No	Hari/ Tanggal	Penyaji	Judul Proposal Penelitian	TTD Moderator	Ket
1.	Jum‟at, 19 Maret 2021	Sri Wulandari	Hubungan Komorbiditas Penyakit Covid-19 Dengen Kejadian Net Death Rate di Rumah Sakit : *Literature Review*	Ani Rasiani, S.Kep., Ners., M.Kep	Pertanyaan mengenai jenis critical appraisal yang digunakan pada penelitian.
2.	Kamis, 25 Maret 2021	Moch. Arif Bachrul Ulum	Hubungan Faktor Individu Dengan Kejadian *Computer Vision Syndrome* pada Mahasiswa S1 Keperawatan Universitas Bhakti Kencana Bandung	Susan Irawan, S.Kep., Ners., MAN	Pertanyaan mengenai cara mencegah CVS pada penelitian.
3	Senin, 7 Juni 2021	Chintya Nervi Ananda	Hubungan Pengetahuan dengan Kesiapan Ibu Usia 40-45 tahun Menjelang Menopuse di Kelurahan Tanjung Aman LK 04 Kotabumi Lampung Utara	R. Nety Rustikayanti, S.Kp., M.Kep	Pertanyaan mengenai instrument yang digunakan pada penelitian.

Lampiran 8

SURAT KETERANGAN BEBAS PLAGIARISME

Universitas Bhakti Kencana

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SURAT KETERANGAN BEBAS PLAGIARISME

Nomor: 028/FKEP.PERP/UBK/VIII/2021

Kepala Bagian Perpustakaan Universitas Bhakti Kencana menerangkan bahwa mahasiswa dengan identitas berikut:

Nama	: Dini Indriyani
NIM	: AK117161
Fakultas	: Keperawatan
Program Studi	: S1 Keperawatan
Nilai Hasil Plagiat	: 10%
Judul KTI/Skripsi	: Pengaruh Penggunaan Earplug dan Eye Mask terhadap Kualitas Tidur Pasien di Ruang ICU.

Dinyatakan sudah memenuhi syarat batas maksimal plagiasi kurang dari 30% pada setiap sub bab naskah KTI/Skripsi yang disusun. Surat Keterangan ini digunakan sebagai syarat untuk pengambilan Ijazah dan Transkrip Nilai.

Bandung, 13 Agustus 2021

Ka. Bagian Perpustakaan UBK

Rosy Rosytasary, S.IIP

Lampiran 9

DAFTAR RIWAYAT HIDUP

I. Identitas Diri

1.	Nama	:	Dini Indriyani
2.	NIM	:	AK.1.17.161
3.	Tempat/Tanggal Lahir	:	Bandung, 9 April 1999
4.	Agama	:	Islam
5.	Anak Ke-	:	2 (Dua) dari 2 (Dua) Bersaudara
6.	Status Perkawinan	:	Belum Menikah
7.	No. Hp	:	0895-332-700-994
8.	E-mail	:	dinindryn99@gmail.com
9.	Alamat	:	Kp. Babakan Satia RT 03 RW 08 Desa Srirahayu Kec. Cikancung Kab. Bandung
10.	Motto Hidup	:	*Start now. Start where you are. Start with fear. Start with pain. Start with doubt. Start with hands shaking. Start with voice trembling. But start, start and don't stop.*

Start where you are, with what you have.

Just…start.

II. Identitas Orang Tua

1. Nama Ayah : Usup Supyani
2. Nama Ibu : Neni Martini
3. Alamat : Kp. Babakan Satia RT 03 RW 08 Desa Srirahayu Kec. Cikancung Kab. Bandung

III. Riwayat Pendidikan

1. SDN Sindangsari 1 : Tahun 2005 - 2011
2. SMPN 3 Cikancung : Tahun 2011 - 2014
3. SMA Bina Muda Cicalengka : Tahun 2014 – 2017
4. Universitas Bhakti Kencana Bandung
   Program Studi Sarjana Keperawatan : Tahun 2017 s.d Sekarang

Lampiran 10

SAMPEL ARTIKEL

Jurnal Keperawatan Indonesia, 2019, 22 (2), 129–138
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PENERAPAN *EVIDENCE-BASED NURSING* PENGARUH *EARPLUG* DAN *EYE MASK* TERHADAP KUALITAS TIDUR PADA PASIEN DI ICU

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Abstrak

Gangguan tidur di ICU disebabkan oleh banyak faktor, diantaranya lingkungan, kebisingan, pencahayaan, kegiatan perawat, penyakit yang diderita, tindakan keperawatan, terapi obat, dan ventilasi mekanik. Efek yang ditimbulkan akan memengaruhi fungsi kekebalan tubuh, sistem metabolisme, regulasi sistem saraf pusat, dan kondisi psikologis. Tujuan penelitian ini menerapkan dan membuktikan efektifitas penggunaan *Earplug* dan *Eye Mask* dalam meningkatkan kualitas tidur pada pasien di ICU. Desain yang digunakan *randomized controlled trial* (RCT) *crossover design.* Peneliti membagi Group A dan Group B dengan *simple random sampling.* Jumlah sampel 24 responden. Instrumen kualitas tidur menggunakan *Richard Campbell Sleep Questionnaire* (RCSQ). Data dianalisis dengan uji *Independent Sample T-Test.* Hasil penelitian didapatkan *p-value* < 0,05, berarti pada alpha 5% terdapat perbedaan yang signifikan kualitas tidur antara malam pertama dan kedua pada masing-masing group sehingga disarankan dijadikan *evidence based* di rumah sakit sebagai salah satu terapi komplementer yang dapat dijadikan intervensi mandiri keperawatan untuk membantu mengatasi gangguan tidur.

Kata Kunci: *earplug, eye mask,* ICU, kualitas tidur

Abstract

Evidence-Based Nursing Application Effect of Earplugs and Eye Mask on Quality Sleep in Patients in ICU*. Sleep disorders in ICU are caused by many factors, including environment, noise, lighting, nursing activities, illness, nursing, medication therapy, and mechanical ventilation. The effects will affect the immune function, metabolic system, central nervous system regulation, and psychological conditions. The purpose of this study to apply and prove the effectiveness of the use of Earplug and Eye Mask in improving sleep quality in patients in ICU. The design used randomized controlled trial (RCT) crossover design. The researchers divide Group A and Group B by simple random sampling. The Total sample of 24 respondents. Sleep quality instrument using Richard Campbell Sleep Questionnaire (RCSQ). Data were analyzed by the Independent Sample T-Test. The result of this research is p-value <0,05, mean at alpha 5% there is a significant difference of sleep quality between first and second night in each group so it is suggested to be an evidence-based in a hospital as one of complementary therapy which can be made independent intervention nursing to help overcome sleep disorders.*

Keywords*: earplug, eye mask, ICU, sleep quality*

Pendahuluan

Pasien yang dirawat di ruang ICU mengalami perubahan pada tidurnya dimana pasien yang mengalami sakit kritis mengalami jam tidur singkat sehingga membuat pasien mengalami kesulitan pencapaian REM dan tidur yang dalam, mengakibatkan pasien mudah terbangun (Weinhouse & Schwab, 2006). Pasien yang menjalani perawatan di ruang ICU, banyak yang mempunyai pengalaman gangguan tidur, penyebabnya diantaranya akibat kebisingan, pencahayaan, intervensi yang diberikan serta pengobatan (Elliott, McKinley, & Eagerm 2010).

Pasien kritis yang menjalani perawatan di ruang ICU dan mengalami gangguan tidur, umumnya digunakan sedasi untuk meminimalkan kegelisahan dan nyeri yang dapat mengganggu kebutuhan tidur pasien. Penanganan gangguan tdur pada pasien kritis dengan farmakoterapi menurut Asnis, Thomas, dan Henderson (2016) dan *Food and Drug Administration* (FDA) sejak tahun 2005 menyetujui penggunaan semua hipnotik tanpa membatasi durasinya, diantaranya adalah golongan obat Benzodiazepin, diantaranya Lorazepam, Midazolam, dan Diazepam (FDA, 2017; Oldham & Pisani, 2015). Terapi lain yang direkomendasikan adalah akupunktur, teknik pijatan pada tubuh*, mind body techniques,* pijat, dan metode lain yang dapat membantu meringankan gejala dan meningkatkan kondisi kesehatan fisik serta mental (Deng & Cassileth, 2005; Potter & Perry, 2011).

Penanganan gangguan tidur pasien di ICU dapat diatasi dengan mengatur sistem pencahayaan, dengan tingkat pencahayaan lingkungan yang tepat dalam membantu pasien menimbulkan perasaan tenang dan nyaman (Engwall, Fridh, Johansson, Bergbom & Lindhal, 2015). Cara lain yang digunakan adalah dengan memodifikasi lingkungan yaitu menurunkan suara percakapan, menurunkan pencahayaan, mengatur kegiatan rutin perawatan di malam hari (Hardin, 2009).

Earplug dan *Eye Mask* adalah suatu cara yang relevan dan logis menutup telinga dan masker penutup mata yang dapat digunakan untuk mencegah terbangunnya saat tidur yang disebabkan oleh rangsangan eksternal. *Earplug* dan *Eye Mask* merupakan intervensi keperawatan yang dapat dilakukan untuk mengurangi gangguan tidur pasien untuk mempertahankan ritme sirkadian secara normal (Demoule, et al., 2017). Hal ini didukung hasil penelitian pada 45 pasien (20 pada kelompok intervensi, 25 pada kelompok kontrol) menunjukkan adanya peningkatan signifikan diantara kelompok-kelompok yang tidur lelap, tertidur, terbangun, terjaga dari tidur lagi. Kualitas tidur yang dirasakan lebih baik pada kelompok intervensi dengan p< 0,05 (Huang & Zheng, 2015). Penelitian lain juga menunjukkan bahwa ada hubungan yang signifikan antara kualitas tidur sebelum dan setelah diberikan intervensi *Earplug* dan *Eye Mask* dengan p <0,001 (Bajwa, Saini, Kaur, Kalra, & Kaur, 2015).

Penggunan *Earplug* dan *Eye Mask* aman dilakukan pada pasien jantung koroner. Selain aman, *Earplug* dan *Eye Mask* juga terbukti efektif untuk menilai kualitas tidur pasien, hemat biaya, mudah diterapkan pada kelompok besar, dan dapat ditoleransi dengan baik oleh tubuh. Penggunaan *Earplug* dan *Eye Mask* juga merupakan metode yang mudah dan murah untuk meningkatkan persepsi dan kualitas tidur pada pasien yang dirawat di ICU (Mashayekhi, Arab, Abazari, Rafati, & Rafiei 2013). Hasil penelitian lain juga menunjukkan bahwa implementasi penggunaan *Earplug* dan *Eye Mask* post operasi kardiotoraks adalah efisien dan mudah. *Earplug* dan *Eye Mask* meningkatkan kualitas tidur serta kepuasan pasien dan dapat mengurangi intensitas nyeri. Selain itu juga *Earplug* dan *Eye Mask* terbukti dapat berkontribusi untuk pemulihan yang lebih cepat, morbiditas yang lebih sedikit, dan mengurangi biaya (Menger, et al., 2018).

Penelitian ini penting untuk dilakukan karena *Earplug* dan *Eye Mask* dapat memberikan pengaruh yang sangat besar pada fisik dan psikologis pasien. Pengaruh *Earplug* dan *Eye Mask* 6-MWT terhadap fisik, yaitu berupa peningkatan kualitas tidur. Sedangkan pengaruh terhadap psikologis, yaitu berupa kemampuan melakukan aktivitas fisik dengan tenang tanpa adanya kecemasan serta kemampuan kognitif dan emosional berfungsi dengan baik. Pengaruh pada sosial, karena hal tersebut akan berkaitan erat dengan kenyamanan pasien.

Metode

Desain penerapan EBN ini adalah *randomized controlled trial* (RCT) *crossover design*. Peneliti membagi dua group yaitu Group A dan

Group B dengan *simple random sampling.* Pemilihan sampel dilakukan dengan mengambil data awal yang sesuai dengan kriteria inklusi kemudian dilakukan skrining pengukuran kualitas tidur dengan RCSQ. Hasil skrining pengukuran kualitas tidur pada Group A dari 24 responden, didapatkan 17 responden yang memiliki kualitas tidur < 25 mm. Sedangkan hasil skrining pengukuran kualitas tidur pada Group B dari 21 responden, didapatkan 15 responden yang memiliki kualitas tidur < 25 mm. Setelah itu dari hasil skrining tersebut akan dipilih menjadi responden dengan menggunakan tabel acak yang dihasilkan oleh komputer didapatkan 24 responden yang terbagi menjadi Group A (n= 12) dan Group B (n= 12) pada 7–9 Mei 2018 di Ruang *Intensive Medical* dan *Surgical* Rumah Sakit Jantung dan Pembuluh Darah Harapan Kita (RSJPDHK) Jakarta. Group A untuk malam pertama diberikan intervensi penggunaan *Earplug* dan *Eye Mask* mulai pukul 21.00–06.00 WIB, kemudian malam kedua tidak diberikan perlakuan *(routine environment).* Sedangkan Group B untuk malam pertama tidak diberi perlakuan *(routine environment*), kemudian malam kedua diberikan intervensi penggunaan *Earplug* dan *Eye Mask* mulai pukul 21.00–06.00 WIB. Setelah intervensi diberikan, kemudian mengukur nyeri dan kualitas tidur pasien dengan menggunakan alat ukur VAS *(Visual Analg Scale)* dan *Richard Campbell Sleep Quationare* (RCSQ). Penerapan EBN ini telah mendapatkan izin dari FIK UI dan RS-JPDHK. Penelitian ini menggunakan analisis univariat dan bivariat menggunakan uji *Inde-pendent Sample T-Test.*

Hasil

Berikut ini adalah gambaran karakteristik responden yang meliputi jenis kelamin, usia, status nyeri, dan lama rawat dapat dilihat pada Tabel 1.

Berdasarkan Tabel 1 diketahui bahwa dari 12 responden pada Group A sebagian besar berjenis kelamin laki-laki yaitu sebanyak 7 responden (58,3%). Pada Group B diketahui bahwa dari 12 responden sebagian besar juga berjenis kelamin laki-laki yaitu 8 responden (66, 7%). Berdasarkan kategori usia diketahui bahwa dari 12 responden pada Group A sebagian besar memiliki usia 41–65 tahun yaitu 7 responden (58,3%). Pada Group B diketahui bahwa dari 12 responden sebagian besar yang memiliki usia 41–65 tahun yaitu sebanyak 7 responden (58,3%). Berdasarkan status nyeri responden diketahui bahwa dari 12 responden pada Group A sebagian besar nyeri ringan yaitu sebanyak 9 responden (75,0%) dan pada Group B diketahui dari 12 responden sebagian besar nyeri sedang yaitu 10 responden (83,3 %). Berdasarkan lama rawat responden diketahui bahwa dari 12 responden pada Group A dan B sebagian besar < 3 hari yaitu sebanyak 8 responden (66,7%) dan 7 responden (58,3%).

Tabel 1. Jenis Kelamin, Usia, Status Nyeri, Lama Rawat

Variabel	Group A		Group B		Total	
	n	%	n	%	n	%
Jenis Kelamin						
Laki-laki	7	58,3	8	66,7	15	62,5
Wanita	5	41,7	4	33,3	9	37,5
Usia						
18–40 tahun	2	16,7	3	25,0	5	20,8
41–65 tahun	7	58,3	7	58,3	14	58,3
> 65 tahun	3	25,0	2	16,7	5	20,9
Nyeri						
Ringan	9	75,0	2	16,7	11	45,8
Sedang	3	25,0	10	83,3	13	54,2
Lama Rawat						
< 3 hari	8	66,7	7	58,3	15	62,5
> 3 hari	4	33,3	5	41,7	9	37,5

Tabel 2. RCSQ Group A Malam Ke-1 dan Malam Ke-2

Measure RCSQ	Group A					
	Malam Ke-1			Malam Ke-2		
	n	Mean	SD	n	Mean	SD
Tidur nyenyak *(Sleep depth)*	12	82,6	4,9	12	41,1	10,3
Persiapan tidur *(Sleep latency)*	12	82,5	5,4	12	41,7	9,1
Terbangun saat tidur *(Awakenings)*	12	83,3	5,3	12	41,9	9,4
Kembali tidur *(Returning to sleep)*	12	82,7	7,7	12	40,7	7,8
Kualitas tidur *(Sleep quality)*	12	83,1	5,0	12	41,8	8.1

Tabel 3. RCSQ Group B Malam Ke-1 dan Malam Ke-2

Measure RCSQ	Group B					
	Malam Ke-1			Malam Ke-2		
	n	Mean	SD	n	Mean	SD
Tidur nyenyak *(Sleep depth)*	12	39,4	14,0	12	78,4	4,5
Persiapan tidur *(Sleep latency)*	12	40,2	13,4	12	77,7	3,8
Terbangun saat tidur *(Awakenings)*	12	40,8	11,9	12	78,6	3,5
Kembali tidur *(Returning to sleep)*	12	38,3	13,5	12	79,1	3,3
Kualitas tidur *(Sleep quality)*	12	38,2	13,3	12	79,6	3,6

Tabel 4. Perbedaan Kualiats Tidur Responden

Group	Kualitas Tidur	n	Mean	SD	SE	95% CI	p
Group A	Malam Ke-1	12	82.8	5.2	1,5	86,2	0,000
	Malam Ke-2	12	41.4	10.4	3,0	48,1	
Group B	Malam Ke-1	12	39.4	13.9	4,0	48,3	0,000
	Malam Ke-2	12	78.7	4.3	1,2	81,4	

Instrumen RCSQ *(Richard Campbell Sleep Questionnaire)* untuk menilai tingkat kualitas tidur. Skala pengukuran terdiri dari 5 item pernyataan dimana setiap item memiliki skala 0–25 (mm) (kualitas tidur yang paling buruk), skala 26–75 (mm) (kualitas tidur yang buruk), sedangkan skala 76–100 (mm) (kualitas tidur yang terbaik).

Tabel 2 menunjukkan pada variabel RCSQ Group A malam ke-1 penggunaan *Earplug* dan *Eye Mask,* nilai tertinggi didapat dari pengukuran —terbangun saat tidur *(Awakenings)"* yaitu nilai rata-rata 83,3. Sedangkan variabel RCSQ malam ke-2 tidak diberikan perlakuan *(routine environment*), nilai tertinggi didapatkan dari pengukuran —terbangun saat tidur *(Awakenings)"* yaitu nilai rata-rata 41,9.

Hasil dalam Tabel 3 menunjukkan bahwa pada variabel RCSQ Group B malam ke-1 dengan *routine environment*), nilai tertinggi diperoleh dari pengukuran —terbangun saat tidur *(Awakenings)"* yaitu nilai rata-rata 40,8. Sedangkan variabel RCSQ malam ke-2 penggunaan *Earplug* dan *Eye Mask,* nilai tertinggi dari pengukuran —kualitas tidur *(Sleep quality)"* yaitu dengan nilai rata-rata 79,6.

Berdasarkan Tabel 4 diketahui bahwa rata-rata kualitas tidur Group A pada malam pertama adalah 82,83 (82,83 ± 5,2) yaitu dengan kualitas tidur terbaik dan malam kedua adalah 41,42 (41,42 ± 10,4) dengan kualitas tidur yang buruk dengan standar deviasi masing-masing 5,2 dan 10,4. Sementara itu rata-rata kualitas tidur Group B pada malam pertama adalah 39,42 (39,42 ± 13,9) dengan kualitas tidur yang buruk dan malam kedua adalah 78,67 (78,67 ± 4,29) dengan kualitas tidur terbaik dengan standar deviasi pada masing-masing group adalah 13,9 dan 4,29. Hasil statistik didapatkan p< 0,05 berarti pada alpha 5% terdapat perbedaan yang signifikan kualitas tidur antara malam pertama dan kedua pada masing-masing group.

Pembahasan

Hasil penerapan EBN penggunaan *Earplug* dan *Eye Mask* didapatkan rata-rata skor tidur di Grup A ditemukan 82,83 ± 5,2 dengan intervensi dan 41,42 ± 10,4 tanpa intervensi. Dalam kelompok B skor tidur ditemukan 39,42 ± 13,9 tanpa intervensi dan (78,67 ± 4,29) dengan intervensi di antara responden. Ada peningkatan yang signifikan (p< 0,01) dalam kualitas tidur setelah intervensi dibandingkan dengan lingkungan rutin (tidak ada intervensi). Temuan di atas sejalan dengan penelitian yang dilakukan oleh Wallace, Robins, Alvord, dan Walker (1999) mengevaluasi efek *Earplug* dan *Eye Mask* pada saat tidur. Penelitian tersebut menggunakan *cross over design* dengan usia rata-rata 25 +/- 3 tahun. Setelah satu malam adaptasi, peserta dibagi menjadi dua kelompok: kelompok pertama mengenakan *Earplug* dan *Eye Mask* dan kelompok kedua tidak. Untuk peserta yang menggunakan *Earplug* dan *Eye Mask*, REM latency (waktu untuk memasuki tidur REM) menurun secara signifikan dan penggunaan penutup *Earplug* dan *Eye Mask* secara signifikan dapat meningkatkan persentase tidur REM.

Efek Lingkungan, pasien-pasien yang dirawat di ICU mayoritas mengalami kecemasan. Mereka jarang sekali memiliki persiapan untuk penerimaan mereka terhadap lingkungan yang baru sehingga pasien merasa bingung dan khawatir. Hal ini terjadi ketika pasien tidak dapat berkomunikasi dengan, dalam keadaan dibius dan pengaruh obat sedatif, atau tidak dapat bergerak dari hambatan kimia atau fisik. Ketakutan dan kekhawatiran tersebut menyebabkan gangguan pada pola tidur dan aktivitas yang rendah. Selain itu, tidur pasien sering terganggu oleh tim perawatan kesehatan untuk prosedur dan penilaian, meskipun peningkatan kecanggihan sistem pemantauan yang harus menurunkan manipulasi tangan dari pasien yang sedang tidur. Kegiatan keperawatan memerlukan lingkungan yang diterangi cahaya. Tidak dapat dipungkiri bahwa kebisingan akan tercipta pada saat perawat mempersiapkan dan melakukan kegiatan perawatan kepada pasien. Dengan demikian, tingkat kebisingan dan cahaya, obat-obatan, nyeri, dan penyakit kritis memengaruhi kualitas tidur dan dapat menyebabkan kurang tidur (Parker, 1995). Kegiatan perawatan pasien, Gabor, et al (2003) menyatakan bahwa aktivitas perawatan pasien, pengukuran tanda-tanda vital, dan pemberian obat-obatan 8 kali/ jam tidur. Sekitar 20% dari kegiatan perawatan pasien akan menyebabkan bangkitan saat tidur. Oleh karena itu, kegiatan perawatan pasien, meskipun sering, bukan merupakan sumber gangguan tidur yang dominan pada pasien ICU (Gabor, 2003).

Tingkat Kebisingan, kebijakan tinjauan eksternal Organisasi Kesehatan Dunia (WHO) tentang kebisingan masyarakat telah menghasilkan panduan yang dapat dapat digunakan untuk mengidentifikasi tingkat kebisingan tertentu di lingkungan rumah sakit. Rekomendasi untuk tingkat kebisingan tidak melebihi 35 dB pada malam hari dan 40 dB di siang hari. Ketika dibandingkan dengan lingkungan yang berbasis lingkungan, intensitas kebisingan di dalam ICU jauh melebihi lingkungan rumah. Hasil penelitian menunjukkan bahwa tingkat kebisingan di Ruang ICU berkisar antara 59 sampai dengan 83 dB, cukup untuk merangsang sistem kardiovaskular dan endokrin serta

mengganggu tidur sebagai akibat dari modulasi stres yang disebabkan oleh kebisingan. Tingkat kebisingan rerata di Ruang ICU adalah sekitar 55 sampai dengan 66 dB, dengan puncak mencapai setinggi 85 dB (Lawson, et al., 2010).

Sumber polusi suara yang berlebihan dalam ruang ICU adalah multifaktor, seperti pada saat memberikan perawatan dan berbagai alat-alat medis yang melekat pada pasien. Mayoritas kebisingan di ICU diciptakan oleh alarm mekanis. Terlepas dari peralatan medis, perawat dan staf perawatan kesehatan lainnya mempunyai tanggung jawab sekitar 80% untuk mengatasi kebisingan yang di ICU. Staf perawat unit perawatan intensif tampaknya memiliki apresiasi atau pengetahuan yang terbatas tentang efek psikofisiologis dari paparan kebisingan; asuhan keperawatan tetap konsisten selama periode 24 jam akan tetapi tingkat pencahayaan pada malam lebih diredupkan. Selain itu, staf keperawatan berpikir bahwa karena mayoritas pasien sakit kritis, dibius, dan ventilasi mekanik, kebutuhan untuk mengurangi kebisingan tidak berlaku. Namun, penelitian Johansson, et al. (2012) menunjukkan bahwa ada kebutuhan untuk mengurangi suara yang mengganggu dan dan suara-suara yang tidak terduga di sekitar pasien yang sakit kritis. Hal tersebut dilakukan dalam rangka untuk memfasilitasi kesejahteraan, tidur, dan pemulihan. Pergeseran dari kondisi hening ke suara yang bising akan mengganggu pasien dan kemudian akan menimbulkan stres (Johansson, et al., 2012).

Selain kelebihan sensor dari kebisingan, pencahayaan juga telah diidentifikasi sebagai faktor yang menyebabkan gangguan tidur. Siklus terang atau gelap yang normal akan membantu mengatur jam biologis dan memainkan peran yang sangat penting dalam mempertahankan siklus tidur sampai seseorang terbangun. Perubahan dalam siklus terang dan gelap memiliki pengaruh besar pada pola tidur karena sekresi melatonin menandakan jam internal tubuh sudah waktunya untuk tidur atau bangun. Cahaya terang, lampu yang tidak redup, dan lampu yang dinyalakan pada malam hari sangat mengganggu tidur pasien (Xie, Kang, & Mills, 2009).

Tingkat cahaya, Siklus terang-gelap merupakan faktor yang paling kuat dalam siklus tidur-bangun manusia yang pada akhirnya pengembangan lingkungan yang tenang. Jika faktor-faktor lingkungan malaadptif, maka siklus tidur-bangun manusia dapat menyimpang dari periode 24 jam normalnya. Bahkan dengan peredupan lampu di ICU, tingkat cahaya pada malam hari di ICU bervariasi dari 5 hingga 1400 lux. Tingkat cahaya antara 100 dan 500 lux diketahui memengaruhi sekresi melatonin dan memiliki efek pada alat pacu jantung sirkadian. Dunn, Anderson, dan Hill (2010) mencatat aktivitas yang terjadi atau tidak terjadi, sementara berbagai sumber cahaya diterangi. Aktivitas yang terkait dengan jumlah terbesar paparan cahaya adalah pada saat pengambilan sampel untuk uji laboratorium, sedangkan aktivitas kedua yang paling sering dicatat saat lampu menyala adalah '‘tidak ada’. ’Hal ini menunjukkan kurangnya kewaspadaan sederhana pada pihak penyedia layanan kesehatan (Dunn, et al., 2010).

Secara teori bahwa kualitas tidur Tidur adalah salah satu kebutuhan dasar manusia yang membutuhkan pelestarian energi, penampilan dan fisik yang baik. Selama tidur, hormon-hormon tertentu seperti serotonin dan hormon pertumbuhan dilepaskan dan perubahan kimia dan peningkatan nutrisi sel terjadi sehingga membuat tubuh siap untuk kegiatan Keesokan harinya. Ini mempromosikan perbaikan, reorganisasi, peningkatan memori, fungsi belajar dan menyebabkan pengurangan stres, kecemasan dan tekanan neurologis dan membantu individu dalam memulihkan energi untuk fokus lebih baik, kemampuan beradaptasi, penyesuaian dan menikmati kegiatan sehari-hari (Daneshmandi, Neiseh, SadeghiShermeh, & Ebadi, 2012). Tidur mungkin tidak mencapai signifikansi bagi seorang individu sampai kurang atau terganggu. Pada saat itu, seseorang dapat menjadi cepat marah, mudah marah, lebih reaktif, dan tidak mampu mengatasi situasi

atau orang secara efektif. Tidur adalah proses yang kompleks dan aktif yang diprogram oleh ritme sirkadian ma-nusia. Jam biologis 24 jam ini didasarkan pada siklus siang–malam, yang program manusia untuk tidur di malam hari dan bangun siang hari (Honkus, 2003). Unit (ICU) adalah bagian dari rumah sakit tempat perawatan, pengobatan, dan obat-obatan yang sangat khusus dan intensif disediakan. Ketika kondisi pasien mengancam jiwa atau rapuh, mereka ditugaskan ke ICU. ICU memastikan pemantauan dan dukungan teknis dan medis yang konstan dan dekat untuk mempertahankan tingkat tubuh normal. Jadi faktor lingkungan seperti kelebihan kebisingan dan pencahayaan, penyakit akut pasien itu sendiri, aktivitas perawatan pasien atau sifat invasif dari prosedur ICU dan ventilasi mekanik merugikan kualitas tidur di ICU (Bourne & Mills, 2004).

Selain kelebihan sensor dari kebisingan, pencahayaan juga telah diidentifikasi sebagai faktor yang mencegah tidur. Siklus terang-gelap yang normal membantu mengatur jam biologis dan memainkan peran penting dalam mempertahankan siklus tidur-bangun. Perubahan dalam siklus terang dan gelap memiliki pengaruh be-sar pada pola tidur karena sekresi melatonin dan menandakan jam internal tubuh bahwa sudah waktunya untuk tidur atau bangun. Cahaya terang dari stasiun perawat, lampu yang tidak redup dan lampu yang dinyalakan pada malam hari semuanya sangat mengganggu tidur pasien (Honkus, 2003). Lampu selalu hadir di unit perawatan kritis dan meskipun peredupan lampu semalam dianjurkan, sejauh mana ini dapat dipelihara dengan aman sering tergantung pada stabilitas pasien. Cahaya terang dapat diperlukan untuk memungkinkan penilaian akurat dari pengamatan pasien, ditambah ini dilengkapi dengan tingkat cahaya yang meningkat lebih lanjut untuk melaksanakan prosedur dan kegiatan perawatan pasien seperti penggantian garis, insersi selokan dada dan perawatan area tekanan penting. Selain itu, cahaya meningkat pada malam hari ketika pasien dirawat atau dipindahkan dan kejadian lain seperti prosedur darurat (Richardson, Allsop, Coghill, & Turnock, 2007).

Hasil penelitian ini juga menunjukkan bahwa kebisingan dan cahaya merupakan faktor utama yang dapat mengganggu tidur pada pasien yang dirawat do ruang ICU. *Earplug* dan *Eye Mask* ditemukan secara signifikan (p= 0,04) berkorelasi dengan kebisingan dan cahaya. Hasil penelitian ini juga didukung oleh Lane dan East (2008) yaitu melakukan sebuah penelitian untuk menggambarkan pengalaman tidur pasien di bangsal bedah dan ICU. Menurut hasil penelitian faktor lingkungan ditemukan sangat berkorelasi dengan gangguan tidur dengan *Pearson's coefficient of* + 0.795. Studi ini menemukan bahwa kebisingan lingkungan, cahaya dan ketegangan merupakan faktor utama yang mengganggu tidur pasien bedah. Temuan ini juga didukung oleh Simons, van den Boogaard, dan de Jager (2012) melakukan penelitian pada pasien yang dirawat di Ruang ICU dan menyimpulkan bahwa untuk pasien perawatan kritis, kombinasi *Earplug* dan *Eye Mask* efektif untuk meningkatkan kualitas tidur. Simons, et al. (2012) juga menganalisis 18 pasien yang dirawat di Ruang ICU yang ditawarkan pilihan memakai *Earplug* dan *Eye Mask* dari jam 10 malam hingga 6 pagi. Pada pasien ini kualitas tidur yang dirasakan meningkat dari 6,6 (5,9 ke 8,2) menjadi 7,5 (7,0 hingga 8,0) (p= 0,041) ketika *Earplug* dan *Eye Mask* itu dipakai.

Penelitian serupa yang dilakukan Zolfaghari, et al. (2013) menunjukkan bahwa efek modifikasi lingkungan pada kualitas tidur di antara pasien ICU. Mereka melaporkan bahwa intervensi mengurangi cahaya dan kebisingan lingkungan yang berlebihan; seperti penggunaan *Earplug* dan *Eye Mask* telah meningkatkan nocturnal pasien tidur di ICU. Hasil penelitian lain yang dilakukan oleh Neyse, Daneshmandi, Sadeghi Sharme, dan Ebadi (2010) menunjukkan bahwa penggunaan *Earplug* dan *Eye Mask* dapat meningkatkan tidur pasien dalam keadaan kritis unit perawatan (Mashayekhi, et al. 2013). Setuju dengan temuan Richardson, et

al. (2007), menggambarkan mayoritas pasien, dalam kelompok non-intervensi (65%) tidur selama 6 jam atau kurang sedangkan, kelompok intervensi (56%) tidur lebih lama dari kelompok kontrol.

Hal ini juga ditunjang penjelasan hasil penelitian dari Elliott, et al. (2010) bahwa pasien yang mengalami perawatan di ruang ICU mengalami gangguan tidur dimana mereka memiliki kualitas tidur yang kurang baik, penyebabnya bisa karena kebisingan, tingkat pencahayaan, tindakan pelayanan medis, pengobatan serta intervensi keperawatan. Menurut Gabor, et al (2003) kegiatan perawatan bagi pasien meliputi, kunjungan perawatan, penilaian tanda-tanda vital dan pemberian obat-obatan yang diberikan saat jam tidur. Sekitar 20% dari tindakan keperawatan mengakibatkan pasien terbangun. Selain itu juga tidak jarang pasien terganggu tidurnya akibat perawat yang memberikan tindakan keperawatan serta monitoring yang dilakukan setiap jamnya, walaupun peralatan ICU canggih, sehingga mengurangi manipulasi tangan terhadap pasien yang sedang tidur (Pulak & Jensen, 2014).

Hambatan yang ditemukan oleh peneliti pada saat menerapkan EBN adalah setiap responden mempunyai kebiasaan tidur yang berbeda saat mengawali tidur, jam saat mulai tidur dan bangun tidur. Hal ini menujukkan bahwa faktor kebiasaan dan budaya tidur akan mempengarhi pola tidur pasien. Disamping itu juga ada beberapa responden yang sesekali mebuka *Earplug* dan *Eye Mask* kemudian tidak berapa lagi dipakai kembali dan kemudian baru tertidur.

Kesimpulan

Hasil penelitian ini telah menunjukkan penggunaan *Earplug* dan *Eye Mask* berimplikasi terhadap kualitas tidur yang lebih baik hal ini dibuktikan hasil uji statistik menunjukkan didapatkan p-*value* < 0,05, berarti pada alpha 5% terdapat perbedaan yang signifikan kualitas tidur antara malam 1 dan 2 pada masing-masing group. Aplikasi kombinasi *Earplug* dan *Eye Mask* merupakan intervensi yang relatif murah dan berharga untuk peningkatan kualitas tidur pada pasien yang di rawat di Ruang ICU. Serta dapat juga digunakan sebagai intervensi alternatif (pengganti obat tidur) bagi pasien yang mengalami kesulitan dalam mengawali proses tidur.

Penggunaan *Earplug* dan *Eye mask* ini dapat digunakan dalam penerapan standar keperawatan pada pasien yang dirawat di Ruang ICU yang mengalami gangguan tidur, dimana tindakan ini tidak menimbulkan efek samping, terjangkau dan mudah untuk diaplikasikan. Selain itu, untuk lebih memaksimalkan hasil pada penerapan terapi ini, maka peneliti menyarankan sebuah studi multisenter dengan ukuran sampel yang lebih besar dapat dilakukan. Studi *Earplug* dan *Eye Mask* bisa dilakukan secara terpisah. *Earplug* dan *Eye Mask* bisa juga digunakan lebih dari satu malam *(From admission to discharge)*. Efektivitas *Earplug* dan *Eye Mask* dapat dinilai dalam area klinis lainnya di rumah sakit. Pengukuran obyektif bisa dilakukan seperti melatonin dan kortisol nokturnal untuk mengevaluasi efektivitas *Earplug* dan *Eye Mask* pada kualitas tidur (BY, DG, TN).

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RESEARCH ARTICLE

EFFECT OF EAR PLUGS & EYE MASK ON SLEEP AMONG ICU PATIENTS: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background: Disturbed sleep and sleep deprivation is common among ICU patients. Use of eye masks and ear plugs may be a valuable to patients attempting to sleep in intensive care units. This randomized control trial aims to assess the efficacy of ear plugs and eye mask in improving the sleep pattern among critically-ill patients.

Method: The study was conducted in January 2014 in selected ICUs of a tertiary care hospital. 100 patients were selected by convenience sampling and were randomized to control and experimental group using parallel group design. The perception of patient's sleep with and without usage of ear plugs and eye mask was evaluated Using Verran and Snyder-Halpern Sleep Scale consists 16 items that include three main sleep sub scales: disturbance, effectiveness, and supplementation.

Results: The study revealed statistically significant difference in mean scores among experimental and control group as per sleep fragmentation (14.6±3.44 vs 4.19±3.58), sleep latency (6.05±1.88 vs 1.70±1.66), sleep quality (10.5±2.52 vs 2.14±2.29), sleep length (8.95±2.47 vs 2.36±2.46), sleep supplementation (11.8±3.26 vs 4.10±2.33).

Conclusion: Findings of the study revealed that ear plugs and eye mask has significantly increased the quality of sleep among critically ill patients at all three subscales (disturbance, effectiveness, and supplementation).

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INTRODUCTION

Sleep is one of the basic human needs required for health and energy conservation, appearance and physical well-being. During sleep, certain hormones such as serotonin and the growth hormone are released and chemical changes and increased cellular nutrition take place so as to make the body ready for the activities of the next day. It promotes repair, re-organization, memory enhancement, learning functions and causes reduction in stress, anxiety and neurological pressures and helps the individual in recovering energy for better focus, adaptability, adjustment and enjoying daily activities (Mohammad *et al.,* 2012). Sleep may not reach significance for an individual until it is lacking or disturbed. At that point, an individual may become short-tempered, irritable, over reactive and unable to cope effectively with situations or people. Sleep is a complex, active process that is programmed by man's circadian rhythm. This 24-hour biological clock is based on a day-night cycle, which programs human to sleep at night and be awake during the day (Honkus, 2003). The Intensive Care Unit (ICU) is the part of the hospital where highly specialized and intensive care, treatment and medicine is provided. When a patient's condition is life-threatening or fragile, they are assigned to the ICU. The ICU ensures constant and close technical and medical monitoring and support to maintain normal body levels. So environmental factors such as excess noise and lighting, the patient's acute illness itself, patient care activities or invasive nature of the ICU procedures and mechanical ventilation are detrimental to quality sleep in the ICU (Bourne and Mills, 2004).

ICU patients were found to have poor sleep quality, which included severe irregularity in circadian rhythm and sleep cycle as well as decreased total sleep and sleep efficiency further compounding their illness (Shu-Yen *et al.,* 2012). Psychological stress alone can temporarily affect an individual's sleep patterns. Research findings has concluded that patients in critical care units may spend 40% to 50% of their sleep time awake and of the remaining sleep time only 3% to 4% in REM sleep (Honkus, 2003). However, Some patients will be predisposed to sleep disturbances in the ICU due to

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chronic illness. Patients with chronic obstructive pulmonary disease have increased sleep latency, reduced total sleep time and experience increased arousals. Cheyne-Stokes respiration is common in patients with chronic heart failure whose ejection fractions are less than 40% and is associated with sleep fragmentation and reduced sleep efficiency. Patients with acute neurological disorders (e.g. intracerebral haemorrhage, meningitis) may also suffer from Cheyne Stokes respiration. Asthmatic patients are known to experience sleep disorders including early awakening (Silveira *et al.,* 2012). The Prevalence of Obstructive sleep apnea is high in Congestive heart failure patients as well as in the general population. So, nursing interventions should be planned to improve sleep quality of Congestive heart failure patients (Patidar *et al.,* 2011).

Noise was the most commonly cited interruption to patients' sleep. Environmental noise in ICU is due to a variety of causes, including ringing phones, talking, beepers and equipment sounds from suction apparatus and mechanical ventilation. Alarms from cardiac monitors, pulse oximeters and ventilators add to the noise pollution. It produces physiologic changes similar to what is seen in a generalized stress reaction, including vasoconstriction, elevated diastolic BP, dilated pupils and muscle tension. Because of adrenalin released by the sympathetic nervous system, these effects prevent the patient from relaxing and falling asleep (Honkus, 2003). The ICU environment makes patients sleep fragmented. A study on factor disturbing sleep found that 40% of ICU patients' awakenings are caused by noise generated by conversations and activities of patient care, which make these very significant factors for sleep disturbances (Silveira *et al.,* 2012).

The noise level in intensive care units (ICUs) ranges from 50 to 75 dB, with the highest night peak level even reaching 103 dB. Besides sensory overload from noise, lighting has also been identified as a factor preventing sleep. The normal light/dark cycles help to regulate the biological clock and play an important role in maintaining wake-sleep cycles. Alterations in the light and dark cycles have a major influence on sleep patterns because of melatonin secretion and signaling the body's internal clock that it is time to sleep or be awake. Bright lights from the nurses' station, lights that are not dimmed and lights that are turned on at night are all very disrupting to patient's sleep (Hui *et al*., 2009).

Besides sensory overload from noise, lighting has also been identified as a factor preventing sleep. The normal light/dark cycles help to regulate the biological clock and play an important role in maintaining wake-sleep cycles. Alterations in the light and dark cycles have a major influence on sleep patterns because of melatonin secretion and signaling the body's internal clock that it is time to sleep or be awake. Bright lights from the nurses' station, lights that are not dimmed and lights that are turned on at night are all very disrupting to patient's sleep (Honkus, 2003). Lights are always present in critical care unit and although the dimming of lights overnight is encouraged, the degree to which this can be safely maintained is often dependent on the stability of the patients. Bright lights can be required to enable accurate assessment of patient observations, plus this is supplemented by further rising light levels in order to carry out procedures and patient care activities such as line replacements, chest drain insertions and essential pressure area care. Moreover, light increases at night when patients are admitted or transferred out and events such as emergency procedures (Richardson *et al*., 2007).

Moreover, there are some adverse consequences of sleep disruption which include impaired immune function, decreased inspiratory muscle endurance and a possible association with delirium and severe morbidity (Rong-fang *et al.,* 2010). Patients in an intensive care unit (ICU) often become confused or delirious soon after or within a few days of admission in the ICU. A research published in Biomed Central's open access journal Critical Care shows that use of earplugs can result in better sleep (as reported by the patients), lower the incidence of confusion, and delay the onset of cognitive disturbances (Bourne and Mills, 2004). Moreover, ICU patients may also have more sleep disturbances caused by both the period of critical care and the high prevalence of concurrent diseases (Orwelius *et al.,* 2008). However, eye masks are also considered as one of the nursing intervention to improve sleep of the patients in CCU's to limit the environmental light as a study revealed that using eye mask, as an economical and uncomplicated method, can improve sleep quality in patients with acute coronary syndrome in the coronary care units and can be used as an alternative method of treatment instead of drug therapy (Mohammad *et al.,* 2012). In addition to this, there is an increasing number of patients have been requesting to use earplugs to help them sleep based on their experiences of wearing them at home or while travelling. Both earplugs and eye masks are regularly offered to travelers on long-haul night-time flights to improve sleep in aeroplanes light and noisy environment (Richardson *et al*., 2007).

Despite much emphasis on the combined effect of ear plugs and eye mask on improvement of sleep quality of patients admitted to ICUs, few studies have been done in this regard and most of conducted studies concerning this issue have particularly emphasized the use of ear plugs and eye mask separately. The present study aimed to determine the impact of ear plugs and eye mask on sleep pattern of patients admitted to ICU.

Hence, the incidence of disturbed sleep is increasing among ICU patients. So, there is urgent need to improve the sleep pattern. As some studies revealed that eye masks and earplugs helped to improve sleep pattern of critically-ill patients but in Indian scenario such studies are very limited. So, the present study has been undertaken in order to assess the efficacy of earplugs and eye mask which helps to improve the sleep pattern of critically-ill patients and to reduce the complication of sleep disruption.

MATERIALS AND METHODS

The study was conducted on 100 patients with 50 subjects in experimental group and 50 in control group in the selected ICU's of DMC & Hospital, Ludhiana. The data was collected during 1st January to 31st January 2014. The permission was taken from the ethical committee of DMC & Hospital to carry out the study. Informed consent was obtained from the patient.

The participants were randomly divided into two groups: with ear plugs and eye mask (experimental group) for 2 successive nights and without ear plugs and eye mask (control group). Then comparison was done to assess the efficacy of ear plugs and eye mask in improving the sleep pattern by taking pre test on 1st day and post test was taken on the 3rd day in both the groups (see Figure 1).

RANDOMIZED CONTROL TRIAL DESIGN
(Parallel group design)

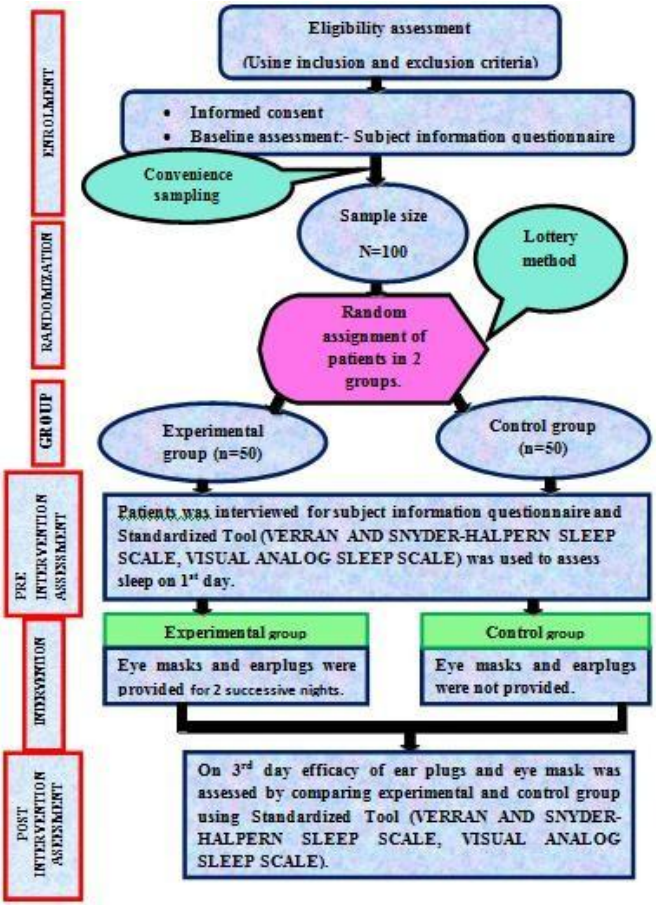

Figure 1. Consortium chart

Data collection tools used in the study way Snyder-Halpern Sleep Scale (VSH Sleep Scale). Using this questionnaire, patients provided an assessment of the quality of their previous night's sleep. This tool consists of 16 items which include three main sleep sub scales: "Disturbance" (interruptions and delays in sleep), "Effectiveness" (how well sleep refreshed the individual) and "Supplementation" (napping). Disturbance comprises items measuring subscales of 'fragmentation' (interruption of sleep) and 'latency' (delay in getting to sleep). Effectiveness comprises the subscales of 'quality' (restfulness and depth of sleep) and 'length' (hours of sleep while in bed). Supplementation contains four items about naps and falling back asleep after morning awakenings. Each characteristic is measured using a 10 cm or 100 mm visual analogue scale. Higher the mean difference ($Mean_D$) score better is the sleep pattern. Analysis of data was done in accordance with the objectives of the study using descriptive and inferential statistics. Calculation has been done using statistical software SPSS (19). Significance of effect or difference was established at the level of 0.05 levels.

RESULTS

The mean age of patients was 58.7 ± 1.54 (Range: 22-88 years). Table 1 shows patients demographic characteristics which showed that out of 50 experimental 23 (46%) were found in age group 61-80 years as compared to control 23 (46%) were found in age group 41-60 years. Nearly half i.e. 51% of the individuals were male. It was found that maximum number of individuals i.e. 60% belonged to urban community. In experimental and control group 24 (48%) and 25 (50%) individuals had secondary level of education respectively. Maximum number of individuals i.e.71% were non-working and 72% individuals were vegetarian. Furthermore, it was found that maximum number of individuals was from ICCU i.e. 55%. In both the groups 20 (40%) of individuals were having 5-8 days of hospitalization and 24 (48%) of individuals were having 1-4 days of hospitalization and maximum number of individuals were present with cardio problems in both experimental and control group i.e. 49%.

Table 1. Distribution of subjects as per socio-demographic characteristics among experimental and control group

Variables	Experimental group (n=50)	Control group (n=50)	Total (n=100)	χ^2 statistics
	f (%)	f (%)	f (%)	
Age (in years)	06 (12)	08 (16)	14	$\chi^2 = 2.72$
21-40	18 (36)	23 (46)	41	df = 3
41-60	23 (46)	15 (30)	38	$p = 0.43^{NS}$
61-80	03 (06)	04 (08)	07	
81-100				
Gender				
Male	25 (50)	26 (52)	51	$\chi^2 = 0.04$
Female	25 (50)	24 (48)	49	df = 1
				$p = 0.84^{NS}$

NS: Not significant

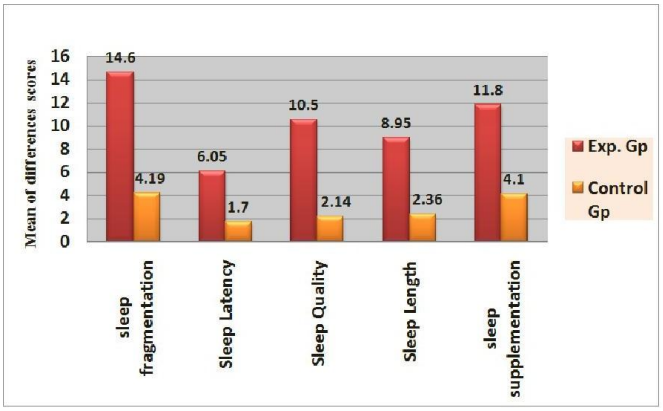

Fig. 2. Mean of differences in sleep pattern among experimental and control group

The mean difference scores as per sleep fragmentation in experimental and control group was 14.6 ± 3.44 vs 4.19 ± 3.58 respectively ($p<0.001$). Whereas, mean difference scores as per sleep latency in experimental and control group was 6.05 ± 1.88 vs 1.70 ± 1.66 respectively ($p<0.001$). Furthermore, sleep

effectiveness is depicted by further two sub-categories i.e. sleep quality and sleep length. The mean difference scores as per sleep quality in experimental and control group was 10.5 ± 2.52 vs 2.14 ± 2.29 respectively (p<0.001). Whereas, mean difference scores as per sleep length in experimental and control group was 8.95 ± 2.47 vs 2.36 ± 2.46 respectively (p<0.001). Moreover, the mean difference scores as per sleep supplementation in experimental and control group was 11.8 ± 3.26 vs 4.10 ± 2.33 respectively (p<0.001). Mean difference scores of these sub scales have been shown in Figure 2.

Sleep disturbance is sub-divided into two parameters i.e. sleep fragmentation and sleep latency. Sleep fragmentation consist of five items i.e. WASO, SS, QD, MSA, MDS and each item represents sleep fragmentation of individuals. Mean difference scores as per item1 i.e. Wake after sleep onset (WASO) in experimental and control group was 2.96 ± 1.13 vs 0.80 ± 0.91 respectively (p<0.001). As per item7 i.e. Soundness of sleep (SS) mean difference score in experimental and control group was 2.87 ± 0.88 vs 0.52 ± 1.05 respectively (p<0.001) while mean difference score as per item8 i.e. Quality of disturbance (QD) in experimental and control group was 2.81 ± 1.19 vs 0.91 ± 0.94 respectively (p<0.001). Mean difference score as per item9 i.e. Mid sleep awakening (MSA) in experimental and control group was 2.99 ± 1.11 vs 1.16 ± 0.83 respectively (p<0.001) and mean difference score as per item11 i.e. Movement during sleep (MDS) in experimental and control group was 2.95 ± 1.20 vs 0.83 ± 0.73 respectively (p<0.001). Whereas, sleep latency consist of two items i.e. SL & QL and each item represents sleep latency of individuals. Mean difference scores as per item6 i.e. Sleep latency (SL) in experimental and control group was 3.02 ± 1.11 vs 0.76 ± 0.84 respectively (p<0.001) while mean difference score as per item10 i.e. Quality of latency (QL) in experimental and control group was 2.99 ± 1.20 vs 0.93 ± 0.98 respectively (p<0.001). (Table 3)

Furthermore, Sleep effectiveness is sub-divided into two parameters i.e. sleep quality and sleep length. Sleep quality consist of three items i.e. RUA, SQS, SSE and each item represents sleep quality of individuals. Mean difference scores as per item12 i.e. Rest upon awakening (RUA) in experimental and control group was 3.44 ± 0.92 vs 0.75 ± 0.76 respectively (p<0.001) while mean difference score as per item14 i.e. Subjective quality of sleep (SQS) in experimental and control group was 3.47 ± 1.18 vs 0.69 ± 1.03 respectively (p<0.001) and mean difference score as per item15 i.e. Sleep sufficiency evaluation (SSE) in experimental and control group was 3.67 ± 1.11 vs 0.71 ± 0.99 respectively (p<0.001). However, sleep length consist of two items i.e. TSP & TST and each item represents sleep length of individuals. Mean difference scores as per item1+2 i.e. Total sleep period (TSP) in experimental and control group was 2.96 ± 1.13 vs 0.80 ± 0.91 respectively (p<0.001) while mean difference score as per item2 i.e. Total sleep time (TST) in experimental and control group was 3.02 ± 0.92 vs 0.81 ± 0.84 respectively (p<0.001).

Moreover, sleep supplementation consist of four items i.e. DTS, AMS, PMS, WAFA and each item represents sleep supplementation of individuals. Mean difference scores as per item3 i.e. Day time sleep (DTS) in experimental and control group was 3.03 ± 1.06 vs 0.96 ± 0.98 respectively (p<0.001) while mean difference score as per item4 i.e. Morning sleep (AMS) in experimental and control group was 2.88 ± 1.16 vs 0.94 ± 0.86 respectively (p<0.001). Mean difference score as per item5 i.e. Afternoon sleep (PMS) in experimental and control group was 2.88 ± 1.17 vs 1.21 ± 0.91 respectively (p<0.001) and mean difference score as per item13 i.e. Wake after final arousal (WAFA) in experimental and control group was 3.04 ± 1.10 vs 1.03 ± 0.87 respectively (p<0.001). So, it was found that the sleep pattern mean difference score among experimental group was significantly higher as compared to control group (p<0.001).

Table 3. Item wise mean difference scores of sleep pattern among experimental and control group

Sleep pattern	Item no.	Experimental group (n = 50)		Control group (n = 50)		t value	p value
		$Mean_D$	SD	$Mean_D$	SD		
• Sleep disturbance:							
Sleep fragmentation							
Wake after sleep onset (WASO)	1	2.96	1.13	0.80	0.91	11.0	0.000*
Soundness of sleep (SS)	7	2.87	0.88	0.52	1.05	13.1	0.000*
Quality of disturbance (QD)	8	2.81	1.19	0.91	0.94	8.20	0.000*
Mid sleep awakening (MSA)	9	2.99	1.11	1.16	0.83	9.48	0.000*
Movement during sleep (MDS)	11	2.95	1.20	0.83	0.73	9.82	0.000*
Sleep latency							
Sleep latency (SL)	6	3.02	1.11	0.76	0.84	10.8	0.000*
Quality of latency (QL)	10	2.99	1.20	0.93	0.98	9.50	0.000*
• Sleep effectiveness:							
Sleep quality							
Rest upon awakening (RUA)	12	3.44	0.92	0.75	0.76	17.5	0.000*
Subjective quality of sleep (SQS)	14	3.47	1.18	0.69	1.03	12.5	0.000*
Sleep sufficiency evaluation (SSE)	15	3.67	1.11	0.71	0.99	15.4	0.000*
Sleep length							
Total sleep period (TSP)	1+2	2.96	1.13	0.80	0.91	11.0	0.000*
Total sleep time (TST)	2	3.02	0.92	0.81	0.84	13.1	0.000*
• Sleep supplementation:							
Day time sleep (DTS)	3	3.03	1.06	0.96	0.98	9.80	0.000*
Morning sleep (AMS)	4	2.88	1.16	0.94	0.86	10.8	0.000*
Afternoon sleep (PMS)	5	2.88	1.17	1.21	0.91	8.18	0.000*
Wake after final arousal (WAFA)	13	3.04	1.10	1.03	0.87	10.0	0.000*

DISCUSSION

Sleep is an important aspect of the healing process. However, sleep impairment is a common problem in hospitals. In order to evaluate the effects of ear plugs and eye mask in improving the sleep pattern of critically-ill patients. Our results showed that in general, patient's sleep pattern was significantly improved after use of ear plugs and eye mask in experimental group. Quality of sleep in hospitalized patients should be a routine part of patients assessment because the patients sleep quality may reveal more information about the patients overall well-being. The results of present study showed that the mean difference score was significantly increased in experimental group as compared to control group which means that sleep was improved after application of ear plugs and eye mask (p=0.000) this was in accordance with the study results of Mashayekhi F *et al.* (2013) Using ear plug statistically significantly increased the quality of sleep ($p<0.05$). This present study also showed that mean difference score of rest upon awakening (RUA) was 3.44 vs 0.75 (p=0.000), subjective quality of sleep (SQS) was 3.47 vs 0.69 (p=0.000), sleep sufficiency evaluation (SSE) was 3.67 vs 0.71 (p=0.000), total sleep period (TSP) was 2.96 vs 0.80 (p=0.000) and total sleep time (TST) was 3.02 vs 0.81 (p=0.000) among experimental and control group respectively. Hence, it was concluded that sleep quality and sleep length was significantly improved in experimental group as compared to control group.

Similar study conducted by Zolfaghari *et al.* (2013) revealed the effects of environmental modification on quality of sleep among CCU patients. They reported that interventions of decreasing excessive environmental light and noise; such as use of earplug and eye mask has improved the patient's nocturnal sleep in CCU. Neyse *et al.* (2010) reported that the use of earplug and eye mask could improve patients' sleep in critical care unit (Mashayekhi *et al*. 2013). In agreement with our finding, Richardson *et al.* (2007) depicted that majority of patients, in non-interventional group (65%) slept for 6 hours or less whereas, interventional group (56%) slept for longer hours than non-interventional group.

From the above discussion, it is concluded that application of ear plugs and eye mask shows significant effect in improving the sleep fragmentation, sleep latency, sleep quality, sleep length and sleep supplementation of critically-ill patients admitted in ICU's than the control group and it should be recommended for improving the sleep pattern in ICU patients.

Conclusion

Sleep is one of the important elements in human life which is associated with reconstruction of physical and emotional power. Maintaining regular sleep cycles is absolutely necessary in order to preserve fitness and health.

Application of ear plugs and eye mask shows significant effect in improving the sleep fragmentation, sleep latency, sleep quality, sleep length and sleep supplementation of critically-ill patients admitted in ICU's than the control group (p=0.000) and is considered as cost-effective and un-complicated method that can improve sleep pattern of critically-ill patients admitted in ICU's.

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ORIGINAL ARTICLE

Effect of Nighttime Earplugs and Eye Masks on Sleep Quality in Intensive Care Unit Patients

Pureepat Arttawejkul[1], Sirimon Reutrakul[2], Dittapol Muntham[3], Naricha Chirakalwasan[4]

Abstract

Purpose: Poor sleep quality in intensive care unit (ICU) can be associated with poor outcome. Excessive noise and lights in ICU are known to disrupt patients' sleep by causing arousals.

Study design: A prospective randomized controlled study.

Materials and methods: The patients admitted to the medical ICU were prospectively included and randomized to receive earplugs and eye masks or no intervention during their first 5 nights in ICU. Their arousal index and other sleep parameters were measured during the first night by polysomnography. Secondary outcomes including wrist actigraphy profiles and subjective sleep quality were recorded during all study nights.

Results: Seventeen patients were enrolled. Eight patients were randomized to earplugs and eye masks group and nine patients were randomized to control group during their first 5 nights in the ICU. The use of earplugs and eye masks demonstrated the trend toward lower arousal index during the first night (21.15 (14.60) vs 42.10 (18.20) events per hour, $p = 0.086$) and increased activity index (activity count/hour) (16.12 (7.99) vs 10.84 (10.39) count/hour, $p = 0.059$) compared to control group. Polysomnography and actigraphy did not demonstrate good agreement.

Conclusion: The use of earplugs and eye masks has a trend toward reduction in arousal index and increased activity in patients admitted to ICU. Limited sample size most likely explained insignificant difference in outcomes. Wrist actigraphy did not accurately measure sleep parameters in ICU patients.

Trial registration: www.clinicaltrials.in.th, TCTR20170727003.

Keywords: Delirium, Earplugs, Eye masks, Intensive care unit, Light and noise control, Sleep quality.

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Introduction

Sleep during critical illness is known to be poor[1] secondary to several factors including pain, anxiety, medication side effect, ventilator dyssynchrony, and nurse's intervention.[2] Noises and light disturbances are known to disrupt sleep in intensive care unit (ICU).[3] The noise in the ICU was demonstrated to be in part responsible for sleep–wake abnormalities.[1] Theoretically, poor sleep quality may reduce muscle endurance resulting in prolonged weaning.[4] Delirium can also be observed with sleep deprivation in ICU associated with increased mortality and long-term cognitive function impairment.[5] Furthermore, sleep deprivation may also reduce immune response and increase risk of nosocomial infection.[6]

Intervention to improve sleep quality in ICU includes medical and nonmedical interventions.[7] However, sedation should be used cautiously due to potential prolongation of mechanical ventilation.[8] Environmental modifications were demonstrated to improve perceived sleep quality and cognition.[9] Ambient light and noise reduction were proven to improve sleep quality.[10] However, these modalities may require complicated hospital environmental and work schedule modification.

Simple interventions including earplugs and eye masks have been shown to be beneficial in postoperative patients in surgical ICU. In this study, the intervention group was observed to have better sleep quality, required less hypnotics and analgesics, and less delirium.[11] Currently, there have been no studies using these simple interventions in medical ICU. Given different patient characteristics and environmental factors between surgical and medical ICU, we aimed to study the effect of earplugs and eye masks on sleep quality and related ICU outcomes in medical ICU setting.

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Conflict of interest: None

Materials and Methods

The study was a randomized controlled trial. The patients admitted to medical ICU (single unit, total of 16 beds) and expected to remain

in ICU for at least 24 hours who were at least 18 years of age, able to understand Thai, and can communicate with investigator, and Glasgow coma score ≥13, Richmond agitation–sedation score was −1 to +1, and did not require medication or intervention to facilitate sleep were enrolled in our study within 24 hours of their ICU admission. Exclusion criteria were bilateral deafness, bilateral blindness, severe encephalopathy, severe dementia, hepatic encephalopathy, uremic encephalopathy, encephalitis, increased intracranial pressure, metabolic derangements, severe hemodynamic instability, high vasopressor requirement (dopamine > 15 μg/kg/minute, epinephrine > 0.1 μg/kg/minute, and norepinephrine > 0.1 μg/kg/minute for at least 1 hour), and severe respiratory failure (PaO_2/FiO_2 < 100). Our medical ICU work environment includes nurse to patient ratio of 1:1 (8-hour shift) and standard hospital environment including 24-hour hospital lightings and no sound level control. The patients were randomized by stratified block randomization to receive earplugs and eye masks or to be in control group.

Intervention

In the study group, the patients were given earplugs (noise reduction rating of 32 dB) and cloth eye masks by physician or nurse during sleep at nighttime according to their habitual home bedtime but not after 22:00 hours. Earplugs and eye masks were removed at 07:00 hours on the following morning. Earplugs and eye masks were allowed to be removed for no longer than 10 minutes for communication if needed. If the patients did not wish to continue with the use of these interventions, they were allowed to inform the nurse (verbal communication if not intubated and bell ringing if intubated) and the inventions can be stopped upon patient request. The patients were informed to use earplugs and eye masks every night during the ICU stay. We also obtained therapeutic intervention scoring system (TISS-28 score) in order to monitor the nurse's activity involving in medical care for each patient.[12]

Polysomnography

During the first night of the admission to the ICU, both study group and control group underwent type I polysomnography conducted in medical ICU. The polysomnography was conducted using standard EEG including frontal leads (F1, F2), central leads (C3, C4), occipital leads (O1, O2), and reference leads at mastoids (M1, M2), electromyography, and electrooculography methodologies. The polysomnography was conducted at the patient's habitual home bedtime but not after 22:00 hours and the study was concluded at 07:00 hours in the following morning. Sleep stages were scored by board certified sleep medicine specialist blinded to the randomization using 30-second epoch window according to the standard criteria from the American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events, 2016.[13]

Actigraphy

Actiwatch® 2 (Respironics) was worn on patient's nondominant wrist throughout study duration. These monitors use highly sensitive omnidirectional accelerometers to count the number of wrist movements in 30-second epochs. This device also has light sensor, which records the light intensity and report this data in lux. The software scores each 30-second epoch as sleep or wake based on a threshold of activity counts that is estimated using activity within the epoch being scored as well as the epochs 2 minutes before and after that epoch. Total sleep time was defined as the amount of actual sleep obtained at night. Sleep efficiency was the percentage of time in bed spent sleeping. Sleep latency was defined as the time period from bedtime to the first epoch of sleep. Wake after sleep onset was defined as the time spent awake after the patient was asleep and before the patient was awake. All parameters were calculated using Actiware 6.0 software, supplied by the manufacturer. The investigator who scored the Actiwatch's data was blinded to the group allocation and the polysomnography data. The patients wore actigraphy during the entire duration in the study while they were in the ICU.

Questionnaires

Sleep history and sleep quality were obtained using Pittsburgh sleep quality index questionnaire (PSQI)[14] as baseline at the enrollment period. In order to accurately monitor sleep quality in the ICU, both Richard-Campbell sleep questionnaire[15] (RCSQ) and Verran/Snyder-Halpern sleep scale[16] were utilized the following morning after the polysomnography and every morning for 5 days during the ICU stay or terminated earlier if the patient was discharged from the ICU before 5 days. In order to assess for the presence of delirium, CAM-ICU was utilized during the study for 5 days during the ICU stay or terminated earlier if the patient was discharged from the ICU before 5 days.

Primary Outcome of the Study

We aimed to determine the difference in arousal index compared between the group using earplugs and eye masks as primary outcome. We also compared other polysomnographic parameters, actigraphy parameters, sleep quality, the prevalence of delirium, the sedation requirement, duration of mechanical ventilation, rate of nosocomial infection, and duration of ICU stay.

Statistical Analysis

The study was analyzed as intention to treat analysis. Sample size was calculated from arousal index using mean difference between two independent samples derived from Huang et al. paper.[17] We used $\alpha = 0.05$, and $\beta = 0.20$, and calculated to have 6 patients in each arm (total of 12 patients). We also added 30% for dropout rate and another 30% for potential uninterpretable data. Eventually, a total of 20 patients were planned. Quantitative variables were compared between two groups using *t* test or Mann–Whitney *U* test and linear regression analysis. Chi-squared or Fisher's exact test was used to compare proportion between groups. Correlation analysis between polysomnography and Actiwatch parameters was analyzed using Lin's concordance correlation coefficient (0.21–0.40 = fair, 0.41–0.60 = moderate, 0.61–0.80 = substantial, and 0.81–1.00 = almost perfect). STATA v12.1 software was utilized. Descriptive analysis was used for analysis. This study was approved by the Ethics Committee. The study was registered at www.clinicaltrials.in.th (#TCTR20170727003).

Results

During the period of June 2017 to May 2018, a total of 20 subjects were enrolled in the study. Ten patients were randomized to control group and 10 patients were randomized to intervention group (earplugs and eye masks). Two patients in the intervention group were excluded (poor polysomnographic quality and ICU discharge prior to the conduct of polysomnography). One patient in control group was excluded due to uninterpretable polysomnography data. A total of 17 patients were analyzed. Baseline clinical characteristics were similar between two groups. Most of the patients had poor

sleep quality as baseline according to PSQI. Clinical characteristic and information upon admission are listed in Table 1. The most common primary diagnosis for ICU admission was pneumonia.

Arousal index during the first night of the study demonstrated a trend toward lower value in the intervention group compared to control group after adjustment for overnight nursing interventions (TISS-28) (p = 0.086) (Fig. 1).

Other polysomnographic parameters including total sleep time, sleep efficiency, wake after sleep onset, sleep latency, % rapid eye movement (REM) sleep, and % N3 sleep were similar between two groups (Table 2).

Subjective sleep quality according to RCSQ score did not demonstrate the difference between the intervention group and the control group (p = 0.236). The prevalence of delirium, the use of sedation, duration of ICU stay, and duration of mechanical ventilation were not different between two groups (Table 3).

Actiwatch data demonstrates a trend toward more activity in the intervention group (Table 4).

Table 1: Clinical characteristic and information upon admission of control and intervention groups

Clinical characteristics	*Control (n = 9)*	*Intervention (n = 8)*
Sex		
Male, *n* (%)	5 (56%)	6 (75%)
Female, *n* (%)	4 (44%)	2 (25%)
Age (years)	76 (32)*	67 (25)*
BMI	21.23 (5.42)*	21.35 (4.74)*
Sedation use, *n* (%)	1 (11%)	1 (13%)
Smoking (pack-year)	0 (10)*	14 (20)*
Alcohol use, *n* (%)	2 (22%)	1 (13%)
Primary diagnosis, pneumonia (%)	4 (44.4%)	3 (37.5%)
Direct admission to ICU, *n* (%)	5 (56%)	5 (63%)
APACHE II	14 (1)*	15 (7)*
SOFA	2 (2)*	4 (6)*
Pittsburgh sleep quality index	7 (2)*	6 (6)*
Nights in the study	2 (1)*	4 (2)*
TISS-28 score during the first night	19 (3)*	24 (7)*
Light exposure	27.77 (16.93)*	52.68 (48.44)*

*Data was demonstrated in median (IQR)

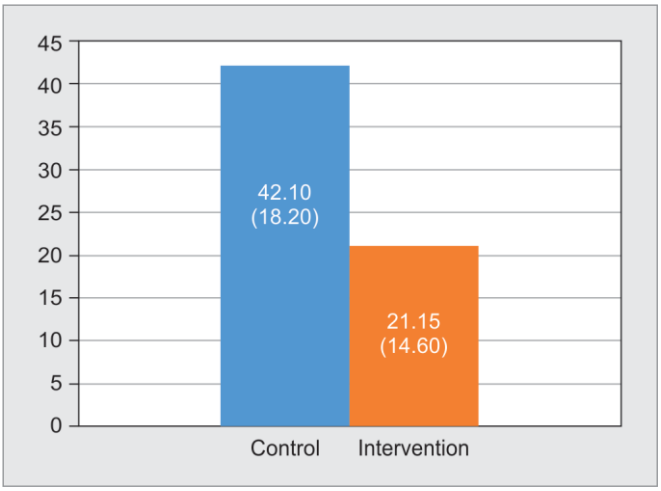

Fig. 1: Arousal index during the first night of the study

Overall correlation between polysomnography and actigraphy was poor to fair. Polysomnography and wrist actigraphy data showed fair agreement on sleep latency (correlation coefficient = 0.389) and sleep efficiency (correlation coefficient = 0.223) but poor agreement on total sleep time (correlation coefficient = 0.188) and wake after sleep onset (correlation coefficient = 0.031). Wake after sleep onset appeared to have the poorest correlation with polysomnography (Table 5).

Discussion

Our study conducted as a randomized controlled trial on the efficiency of the use of earplugs and eye masks and sleep quality

Table 2: Polysomnography data of control and intervention groups

PSG parameter	*Control (n = 9)*	*Intervention (n = 8)*	*p value*§
Total sleep time	333 (112)*	319 (174)*	0.452
Sleep efficiency	77.10 (9.70)*	65.2 (32.85)*	0.891
Wake after sleep onset	114 (107)*	190 (175.5)*	0.698
Sleep latency	14 (21)*	0 (22)*	0.368
REM sleep percentage	6.4 (12.5)*	4.75 (6.45)*	0.608
Slow wave sleep percentage	1.3 (22.1)*	3 (31.6)*	0.961

*Data was demonstrated in median (IQR) which was adjusted for TISS-28
§p value was adjusted for overnight nursing interventions (TISS-28)

Table 3: Clinical outcomes of control and intervention groups

Clinical parameter	*Control (n = 9)*	*Intervention (n = 8)*	*p value*
RCSQ score	56.4 (5.17)§	58.5 (5.26)§	0.236
Delirium	1 (11.1%)	1 (12.5%)	1.000
Sedation use	0 (0%)	1 (12.5%)	0.471
ICU duration (hours)	68 (20)*	96 (66.5)*	0.572
Mechanical ventilation (hours)	63.5 (58)*	72.5 (47.5)*	0.925
Nosocomial infection	0 (0%)	0 (0%)	–

*Data was demonstrated in median (IQR)
§Data was demonstrated in mean (SD)

Table 4: Activity data from Actiwatch of control and intervention groups

Actiwatch parameter	*Control (n = 9)*	*Intervention (n = 8)*	*p value*
Activity count	2529.25 (887.23)*	5872.95 (2611.53)*	0.093
Activity index**	10.84 (10.39)*	16.12 (7.99)*	0.059

*Data was demonstrated in median (IQR)
**Activity index = activity count per hour

Table 5: Correlation of actigraphy parameters and polysomnography parameters

Polysomnography parameter	*Actigraphy parameter*	*Correlation coefficient*
Total sleep time	Actual sleep time	0.188
Sleep efficiency	Sleep efficiency	0.223
Wake after sleep onset	Wake after sleep onset	0.031
Sleep latency	Sleep latency	0.389

in real medical ICU using polysomnography. The previous studies measured sleep quality only by subjective questionnaire.[18-20] Three previous studies using polysomnography were conducted in healthy subjects in simulated ICU environment.[17,21,22] One study was conducted with earplugs[21] and two studies were conducted with earplugs and eye masks.[17,22] All previous studies using objective polysomnography to measure the efficacy of earplugs and eye masks on sleep quality in ICU were done only in simulated ICU environment and may not represent the full auditory and visual experience of the ICU.

Our study demonstrated a trend toward lower arousal index 21.15 (14.60) in intervention group compared to 42.10 (18.20) in control group ($p = 0.086$). This finding supports the benefit of noise and light reduction in promoting continuity of sleep in ICU setting. Similar to our finding, Hu et al. studied 14 healthy subjects exposed to recorded ICU noise and light and demonstrated that the use of earplugs and eye masks was associated with reduction in arousal index.[22] Reduction in arousal index may clinically benefit since prior studies demonstrated detrimental effect of arousal.[23-25] Prior study conducted in healthy volunteers demonstrated that arousal index is a single strongest polysomnographic predictor of daytime sympathetic discharge which could pose risk of increased blood pressure.[23] In studies conducted in obstructive sleep apnea population, arousal index was demonstrated to be marker of carotid artery atherosclerosis,[24] risk of acute coronary syndrome, transient ischemic attack, and stroke or death.[25]

Furthermore, our study also demonstrated a trend toward increase in activity with the use of earplugs and eye masks compared to control group ($p = 0.059$). Winkelman et al. studied ventilated subjects in medical and surgical ICU using actigraphy and demonstrated that activity appeared to be associated with a decrease in IL-6 level.[26] The same group also conducted another study in medical ICU and step-down unit on ventilated subjects participated in an early mobility program.[27] The study demonstrated that lower activity count from actigraphy has the negative impact with potential toward alteration in inflammatory profiles.[27] Clinical importance of increased activity of ICU patients was also previously demonstrated. Early immobilization was shown to reduce ICU and hospital lengths of stay,[28] increase ventilator free days,[29] reduce ICU-acquired weakness,[29,30] increase proportion to return to independent function at discharge,[31] reduce proportion of time in ICU with delirium,[31] and improve glycemic control.[30]

Insignificant difference in the outcomes can be explained by several reasons. First, the limited sample size; the calculated sample size was from the study of healthy volunteers wearing earplugs and eye masks in simulated ICU setting with large difference between the intervention group and control group. Statistically, this large difference resulted in small calculated sample. This calculated sample size could have been inadequate since the difference between intervention group and control group in real ICU setting with more disturbing environment could have been less. In fact, larger sample size may be needed to detect the difference in expected outcomes. Second, inhomogeneous baseline characteristics between two groups could be potential explanation. Despite the randomization, the data indicated a trend toward less clinical severity (lower sequential organ failure assessment (SOFA) score) and lower light exposure during sleep observed in the control group compared to the intervention group. These differences may have promoted overall better sleep quality in the control group compared to the intervention group and masked the expected difference in the outcome. Finally, there are potential occult factors, which may have affected the outcome including various medication, procedures, or mode of medical ventilation that were not controlled in our study.

Although wrist actigraphy has long been used to measure sleep in ambulatory patients with great reliability, poor correlation between polysomnography and actigraphy in sleep measurement was in agreement with current evidence in the literature. Actigraphy was observed to be valid and reliable for detecting sleep in healthy adult populations but less reliable for detecting sleep in disturbed setting.[32] Actigraphy may incorrectly score wakefulness as sleeping in ICU patients as they were awake but immobile due to restraints, sedation, or severe illness.[33] Recent systematic review of 13 eligible studies also concluded that since actigraphy only measures gross motor activity, it is not recommended to be used to measure sleep in ICU.[34] Algorithm of software used to analyze this data in actigraphy may have to be corrected for other variables before this device can be used accurately in ICU setting.

Our study suggests that polysomnography is still a gold standard for sleep measurement in ICU setting. Knauert et al. conducted polysomnography in 29 patients in medical ICU and demonstrated sufficient data to determine sleep stage, sleep efficiency, and arousal indices in their studies with 93% interpretable quality.[35] Similarly, our study demonstrated interpretable quality of polysomnography data to be 94%.

Conclusion

Earplugs and eye masks insignificantly reduced arousal index and increased activity in patients admitted to ICU. Limited sample size most likely explained insignificant difference in outcomes in our study and larger sample size is needed. Wrist actigraphy did not accurately measure sleep parameters in ICU patients. To date, polysomnography is still a valid and reliable method to measure sleep parameters in ICU setting.

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Critical Care

RESEARCH Open Access

Impact of earplugs and eye mask on sleep in critically ill patients: a prospective randomized study

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Abstract

Background: Poor sleep is common in intensive care unit (ICU) patients, where environmental factors contribute to reduce and fragment sleep. The objective of this study was to evaluate the impact of earplugs and eye mask on sleep architecture in ICU patients.

Methods: A single-center randomized controlled trial of 64 ICU patients was conducted from July 2012 to December 2013. Patients were randomly assigned to sleep with or without earplugs and an eye mask from inclusion until ICU discharge. Polysomnography was performed on the first day and night following inclusion. The primary outcome was the proportion of stage N3 sleep over total sleep time. Secondary outcomes were other descriptors of sleep and major outcome variables.

Results: In the intervention group, nine (30%) patients did not wear earplugs all night long. The proportion of N3 sleep was 21 [7–28]% in the intervention group and 11 [3–23]% in the control group ($p = 0.09$). The duration of N3 sleep was higher among the patients in the intervention group who wore earplugs all night long than in the control group (74 [32–106] vs. 31 [7–76] minutes, $p = 0.039$). The number of prolonged awakenings was smaller in the intervention group (21 [19–26] vs. 31 [21–47] in the control group, $p = 0.02$). No significant difference was observed between the two groups in terms of clinical outcome variables.

Conclusions: Earplugs and eye mask reduce long awakenings and increase N3 duration when they are well tolerated.

Trial registration: ClinicalTrials.gov, NCT02292134. Registered on 21 Nov 2013.

Keywords: Sleep, Intensive care, Earplugs, Eye mask, Delirium, Polysomnography

Background

Over the past decade, a large body of literature has raised the major issue of sleep disturbances in critically ill patients [1, 2]. Sleep is reduced, fragmented, does not follow the regular circadian rhythm, and contains increased N1-N2 stages, to the detriment of N3 and rapid eye movement (REM) sleep. Importantly, N3 and REM sleep play a critical role in many physiologic functions, including the central nervous, cardiovascular, endocrine, respiratory, and immune systems. The deleterious consequences of poor sleep in patients admitted to the intensive care unit (ICU) are becoming increasingly clear [1]. Poor sleep is a risk factor for delirium [3], noninvasive ventilation failure [4], and an intrinsic ICU stressor for patients [5], which may in turn participate in the mechanisms of posttraumatic stress disorder [6]. The impact of poor sleep on immune function, metabolism, length of mechanical ventilation, and post-ICU quality of life is also suspected but has not been clearly demonstrated [7]. Sleep improvement has therefore become a goal of care in the ICU [8].

The multiple mechanisms responsible for altered sleep include environmental factors such as noise and light, including those related to human interventions [9].

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However, the reduction of noise and light during the night, although theoretically feasible, is not easy to achieve in the ICU, because a high level of human activities in the ICU during the night may be required by the condition of admitted patients or the admission of new patients. In addition, for safety reasons, the noise level of alarms cannot always be turned off or even lowered [10]. An alternative strategy would be to protect patients individually against noise and light by means of earplugs and an eye mask. Previous reports have suggested that this strategy could increase sleep quality in healthy subjects submitted to a level of noise and light encountered in an ICU [11] and in patients sleeping in the postanesthesia care unit [12]. However, the impact of earplugs and an eye mask on sleep quality has not previously been evaluated in ICU patients by polysomnography.

We therefore conducted a randomized controlled trial to determine the efficacy of this strategy on the basis of the hypothesis that earplugs and an eye mask would improve sleep quality during the first night following the initiation of the intervention in critically ill patients, as measured by the proportion of N3 sleep, also known as non-REM sleep stages 3 and 4 or slow-wave sleep. We selected this criterion because N3 sleep is not only thought to be the most "restorative" sleep stage [13–15] but also is involved in the pathogenesis of metabolic and cardiovascular diseases [16, 17] and is noticeably reduced in ICU patients [9, 18, 19].

Methods

Human research ethics committee approval for the study was provided by the Comité de Protection des Personnes - Ile de France 6. Patients or their next of kin gave informed consent. Data were collected from July 2012 to December 2013.

Site

This study was conducted in a 16-bed adult general ICU within a 1600-bed hospital in Paris. The ICU is arranged as two rows, one comprising ten rooms and one comprising six rooms, with one patient per room. Each room has the same organizational layout, with one door leading to the common hallway and one wall containing a large window facing either north or south. Three intensivists are responsible for the management of all patients from 8:30 a.m. to 7:00 p.m., and one intensivist covers the night. Ward rounds are conducted by the intensivists three times per day. The nurse-to-patient ratio is between 1:2.5 and 1:3, depending on the intensity of care. Patient care activities occur according to defined schedules.

Sleep quality is an important aspect of care in our unit, and general rules are routinely applied to promote nighttime sleep and to avoid sleep disruption. Lights are generally turned off in rooms and dimmed in corridors at 10:00 p.m. Patient televisions are turned off, in-room alarms are minimized, and care activities are grouped [8]. In addition, window blinds are raised during day, and mobilization is encouraged in order to promote normal circadian rhythms.

Patients

Patients meeting the following criteria were included: (1) no sedation for > 24 h, (2) sedation level < 3 on the Ramsay Sedation Scale, (3) expected remaining ICU stay > 48 h, and (4) morphine < 0.01 mg/kg/minute and norepinephrine < 0.3 μg/kg/minute. Exclusion criteria included a history of sleep disorders such as sleep-related breathing disorders, insomnias, or sleep movement disorders; psychiatric illness requiring chronic medication; a known diagnosis of central neurological impairment; liver disease with encephalopathy; uncontrolled sepsis; severe hearing impairment; or blindness. Patients aged < 18 years were also excluded.

Study design

Randomization was performed using a computer-generated sequence provided through a website. Patients were allocated to one of two different groups: The control group received routine care during the night, and the intervention group received routine care plus an eye mask (Slaapmasker Schlafmaske, Stuttgart, Germany) and earplugs (Samurai, Vandeputte Group, Oosterhout, The Netherlands). The intervention was applied every night at 10:00 p.m. until 8:00 a.m. from inclusion until ICU discharge. Trained nurses placed the devices.

Data collection and analysis

Simplified Acute Physiology Score II and Charlson comorbidity index score [20] were calculated on admission. Physiologic data such as heart rate, arterial blood pressure, respiratory rate, and temperature were also recorded, as were blood gases. The patient's self-reported comfort and sleep quality were assessed daily using a simplified visual analogue scale (VAS; 10 cm horizontally) from zero for worst possible comfort or sleep quality to 10 for best possible comfort or sleep quality. The presence of delirium was evaluated once daily by a nurse using the Confusion Assessment Method for the ICU [21].

Polysomnography was performed on the day of inclusion using a portable device (Dream®; MEDATEC, Anderlecht, Belgium). Recording lasted 18 h, starting at 2:00 p.m. and ending at 8:00 a.m. Electroencephalography (EEG) with electrodes placed at O1/A2 and C4/A1 according to the international 10–20 system, electromyography (electrodes located on the levator menti muscle), electrooculography (left superior canthus, right inferior canthus), electrocardiography, and pulse oximetry were recorded. No video was used. Sleep recordings were

visually scored by a sleep specialist physician blinded to the group using international criteria [22].

Ambient sound was continuously recorded until ICU discharge at the level of the patient's head with a portable sound meter (SL407760; Littoclime, Caen, France). Time with lights on was continuously recorded until ICU discharge by a camera pointing at the ceiling of the patient's room. Number and length of nurse interventions during the night (from 10:00 p.m. to 8:00 a.m.) were recorded until ICU discharge by bedside nurses. Compliance with earplug and eye mask use was recorded by bedside nurses.

At ICU discharge, using a VAS, patients self-assessed overall sleep quality and comfort during their stay. At ICU discharge and at day 90 following randomization, patients were assessed using the Hospital Anxiety and Depression Scale (HADS) [23, 24]. In addition, patients were assessed at day 90 for sleep quality using the Pittsburgh Sleep Quality Index and for posttraumatic stress disorder-related symptoms using the Impact of Event Scale–Revised (IES-R) [25]. Data were recorded on electronic case report forms powered by a data manager (CleanWEB™; Telemedicine Technologies, Boulogne-Billancourt, France).

Statistical analysis

The primary outcome variable was the proportion of total sleep time spent in N3 sleep during the first day and night (from 2:00 p.m. to 8:00 a.m.) following inclusion. Secondary endpoints were sleep quality, REM sleep, sleep efficiency (number of minutes of sleep divided by the number of minutes recorded), index and number of arousals, short awakenings (awakenings lasting < 1 minute) and prolonged awakenings (awakenings lasting > 1 minute), and awakenings during the first day and night following inclusion. Other secondary endpoints were sleep quality measured with a VAS sleep scale; presence of delirium, anxiety, and depression on ICU discharge and on day 90; ICU and hospital length of stay and mortality; presence of posttraumatic stress disorder; and sleep quality on day 90.

On the basis of previous reports of sleep architecture in the ICU [9, 18, 19], we estimated the mean N3 proportion of total sleep time in patients comparable to our study population to be 2.9% with an SD of 3.3%. We assumed that the N3 proportion would increase to 5.8% in patients receiving routine care plus eye mask and earplugs, but that it would remain at 2.9% in other patients. The effect size between these two means was 0.879 on a 0–1 scale. Sample size calculations showed that 25 patients per group would provide 80% power at a two-sided level of 0.05 to detect an N3 increase. With an estimated 25% polysomnography failure rate, the final calculated sample size was 64 patients.

Continuous variables are described using the median and IQR. Categorical variables are described using frequency and percentage. Statistics were performed with SAS version 9.3 software (SAS Institute Inc., Cary, NC, USA).

Differences between groups were assessed with the Mann-Whitney *U* test for continuous variables and the x^2 test for categorical variables. The primary analysis was done on the basis of the intention-to-treat principle. Because we further noticed that a substantial number of patients did not follow the intervention (i.e., did not wear earplugs all night long), we decided to perform a secondary post hoc analysis to compare patients who actually wore earplugs all night long in the control and intervention groups.

Results

Enrollment, study population, and sleep recordings

We prospectively screened patients between July 2011 and December 2013 and 64 patients were enrolled, 32 in each group (Fig. 1). Three patients withdrew consent after randomization, two in the intervention group and one in the control group.

During the first night following inclusion, 21 patients wore earplugs all night long in the intervention group, and 18 of these patients wore their eye mask. Nine patients wore earplugs only part of the night, and one patient wore the eye mask alone. The main reasons for refusing to wear earplugs or the eye mask were discomfort and anxiety.

Baseline patient characteristics are displayed in Table 1. The two study groups were balanced at baseline in terms of age, comorbidities, severity of illness, reason for ICU admission, days of sedation and time from end of sedation to inclusion, length of ICU stay prior to inclusion, physiologic variables, and ventilation and oxygenation parameters (Additional file 1: Table S1). Nurse interventions tended to be lower in the intervention group, and noise level was similar in the two groups (Additional file 2: Table S2).

Primary outcome: sleep architecture

Polysomnography could not be scored accurately, owing to poor signal quality in seven patients in the intervention group and three patients in the control group. These patients were included in the analysis but did not contribute to the primary outcome. Data for the primary outcome variable were subsequently collected for 23 patients in the intervention group and 28 patients in the control group.

Sleep measurements are detailed in Table 2. The N3 proportion was not different between the two groups (21 [7–28]% in the intervention group vs. 11 [3–23]% in the control group, $p = 0.09$). Prolonged awakenings were less frequent in the intervention group (21 [19–26] %)

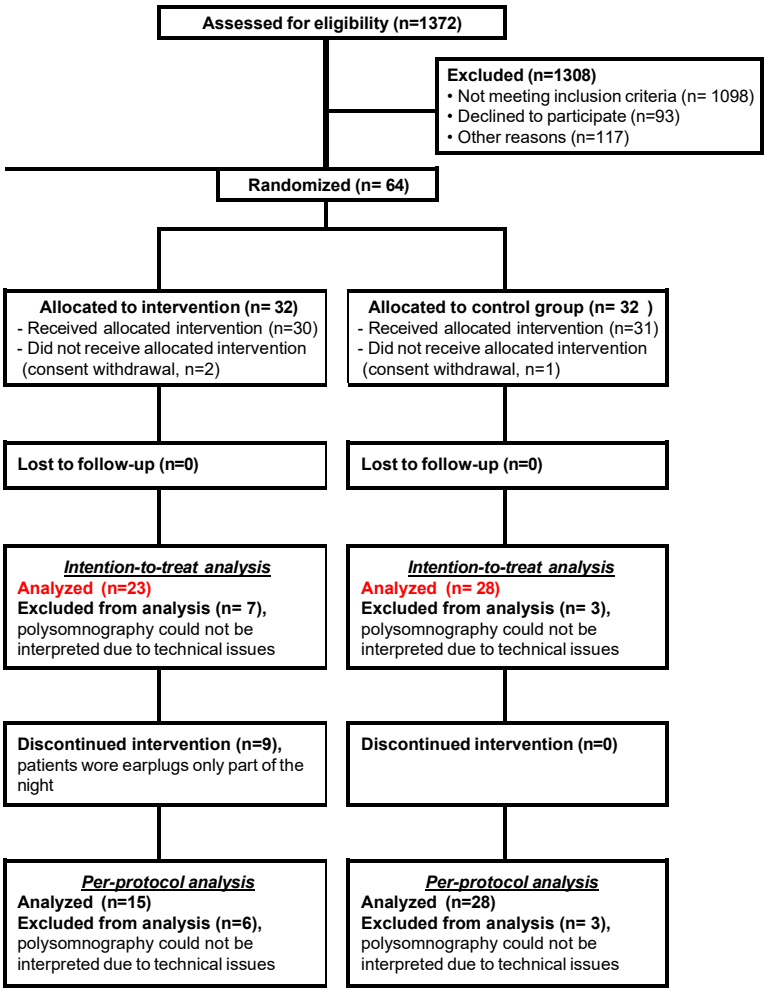

Fig. 1 Study flowchart

than in the control group (31 [21–47] %, $p = 0.02$). Total sleep time during the 18-h recording and during nighttime, REM sleep time and percentage, sleep efficiency, and number of short awakenings (< 1 minute) and arousals were not significantly different between the two groups. Sleep quality following the first night after inclusion was similar in the two groups.

We compared the 31 patients in the control group with the 21 patients in the intervention group who actually wore earplugs all night long in a per-protocol analysis. Among them, polysomnography could be scored in 15 patients (Additional file 3: Table S3). N3 sleep time was higher and prolonged awakenings were less frequent in intervention group patients who wore earplugs all night long than in the control group patients.

Secondary outcomes

In the intervention group, evaluation was performed at ICU discharge in 23 patients, at hospital discharge in 22 patients, and at day 90 in 16 patients. In the control group, evaluation was performed at ICU discharge in 22 patients, at hospital discharge in 21 patients, and at day 90 in 18 patients (Additional file 4: Figure S1).

Table 3 displays the main outcome variables. No significant difference was observed among the intervention and control groups in terms of sleep quality and presence of delirium during the ICU stay. On ICU discharge, VAS-assessed sleep quality and comfort throughout the ICU stay, anxiety and depression, ICU length of stay and mortality, and hospital mortality and length of stay were not significantly different between the two groups. On day 90, anxiety and depression as assessed using the HADS, sleep quality as assessed using the Pittsburgh Sleep Quality Index, and IES-R were not significantly different between the two groups.

Discussion

The main findings of this study can be summarized as follows. Earplugs and an eye mask applied from awaking following interruption of sedation and until ICU

Table 1 Main characteristics of included patients

	Control group (*n* = 31)	Intervention group (*n* = 30)	*p* Value
Patient characteristics			
Age, years	65 (58–74)	64 (54–74)	0.99
Sex, male, *n* (%)	18 (58)	20 (67)	0.48
SAPS II score	45 (27–65)	42 (26–60)	0.60
Charlson comorbidity index score	4 (3–6)	4 (2–5)	0.30
Main reasons for ICU admission, *n* (%)			
Acute respiratory failure	23 (74)	20 (67)	0.71
Pneumonia/ pleural effusion	11	8	
Chronic respiratory disease	4	7	
Cardiogenic pulmonary edema	5	3	
Neuromuscular disease	2	0	
Vascular disease	1	2	
Postoperative care/trauma, *n* (%)	3 (10)	4 (13)	0.96
Metabolic, *n* (%)	3 (10)	4 (13)	0.96
Nonrespiratory sepsis, *n* (%)	2 (6)	2 (7)	0.63
Prior to inclusion			
Days of sedation	3 (2–8)	4 (2–7)	0.30
Time from end of sedation to inclusion, days	3 (0–4)	1 (0–4)	0.49
On inclusion			
RASS	0 (0–0)	0 (0–0)	0.19
Comfort score, VAS	60 (50–80)	70 (50–80)	0.92
Physiologic variables			
Temperature, °C	37.1 (36.9–37.4)	37.1 (36.2–37.6)	0.66
Heart rate, beats/ minute	98 (83–116)	86 (76–108)	0.29
Systolic blood pressure, mmHg	115 (106–140)	130 (121–134)	0.19
Respiratory rate, breaths/minute	22 (20–25)	19 (16–25)	0.18
Analgesic treatment, *n* (%)	17 (55)	11 (37)	0.15
Mechanical ventilation	6 (19)	5 (17)	0.35
Invasive ventilation, *n* (%)	6 (19)	3 (10)	
Noninvasive ventilation, *n* (%)	0	2 (7)	

RASS Richmond Agitation-Sedation Scale, *SAPS II* Simplified Acute Physiology Score II, *ICU* Intensive care unit, *VAS* Visual analogue scale (0 = maximal discomfort, 100 = maximal comfort)
Results are expressed as median (interquartile range) or frequency (%)

Table 2 Main sleep characteristics of the patients in whom polysomnography could be accurately scored

	Control group (*n* = 28)	Intervention group (*n* = 23)	*p* Value
Total sleep time per 18 h[a], minutes	301 (229–398)	290 (146–410)	0.91
Total sleep time during nighttime[b], minutes	274 (177–329)	286 (120–392)	0.77
N1 Stage, minutes	29 (17–59.5)	29 (6–50)	0.42
N2 Stage, minutes	182 (102–229)	146 (84–223)	0.32
N3 Stage, minutes	31 (7–69)	58 (24–86)	0.16
N3 stage, % of total sleep time	11 [3–23]	21 [7–28]	0.09
REM sleep, minutes	32 (6–48)	35 (9–60)	0.64
Sleep efficiency[a], % per 18 h	27 (21–38)	26 (14–42)	0.72
Short awakenings (<1 minute), *n*	11 (5–20)	8 (3–13)	0.23
Prolonged awakenings (>1 minute), *n*	31 (21–47)	21 (19–26)	0.02
Awakenings and arousals, *n*/TST	26 (13–46)	24 (15–29)	0.39
Self-assessed sleep quality, VAS	50 (32–70)	50 (40–60)	0.81

REM Rapid eye movement, *TST* Total sleep time, *VAS* Visual analogue scale from zero (poor sleep quality) to 100 (excellent sleep quality)
[a]Total recording period is from 2:00 p.m. to 8:00 a.m.
[b]Nighttime is from 10:00 p.m. to 8:00 a.m.

discharge (1) failed to significantly increase the proportion of N3 sleep on the first night following inclusion, but significantly decreased the number of prolonged awakenings; (2) were poorly tolerated, but may increase the duration of N3 sleep in patients who tolerate them; and (3) had no impact on outcome.

This study demonstrates that sleep was severely altered in critically ill patients. Sleep alterations involved both sleep duration and architecture and were consistent with previous reports [19, 26, 27], although the time spent in N3 sleep tended to be longer in our study. The severity of sleep alterations observed in this study shows that the study was conducted in patients with poor-quality sleep who were likely to benefit from an intervention designed to improve sleep quality. Of note, one of the strengths of our study was the use of polysomnography as a key outcome measure, because, to our knowledge, this study is one the largest studies including polysomnography recording in critically ill patients [4, 9, 19, 26–32]. However, performing polysomnography to provide analyzable data is a challenge in the ICU, as recently reported [33]. In contrast with recent reports, we did not observe the atypical sleep stages described in ICU patients, namely pathologic wakefulness and atypical sleep [29, 34], because the EEG patterns observed complied with the Rechtschaffen and Kales scoring system [22]. This result could be explained by the exclusion of patients in whom sedation or high-dose opioids

Table 3 Main outcomes at intensive care unit discharge, hospital discharge, and day 90 follow-up

	Control group	Intervention group	*p* Value
At ICU discharge[a]	*n* = 22	*n* = 23	
Self-assessed sleep quality, VAS	60 (25–80)	70 (50–70)	0.63
Self-assessed comfort score, VAS	70 (50–80)	70 (70–80)	0.68
Anxiety score, HADS	9 (6–11)	8 (6–10)	0.66
Depression score, HADS	8 (4–9)	4.5 (2–9)	0.25
Delirium, *n* (%)	2 (6)	2 (7)	1
ICU length of stay, days	7 (5–26)	7 (4–11)	0.18
ICU mortality, *n* (%)	4 (13)	3 (10)	0.99
At hospital discharge[b]	*n* = 21	*n* = 22	
Hospital length of stay, days	26 (14–86)	24 (12–47)	0.76
Hospital mortality, *n* (%)	4 (13)	3 (10)	0.76
At day 90 follow-up[c]	*n* = 18	*n* = 16	
Anxiety score, HADS	6 (4–12)	8 (4–11)	0.69
Depression score, HADS	6 (2–9)	6 (3–12)	0.63
Pittsburgh Sleep Quality Index	5 (5–8)	8 (5–11)	0.25
Impact of Event Scale–Revised	16 (9–27)	11 (5–18)	0.15

ICU Intensive care unit, *VAS* Visual analogue scale from zero (poor) to 100 (excellent), *HADS*, Hospital Anxiety and Depression Scale
Results are expressed as median (IQR) or frequency (%)
[a]Six patients died in the ICU, and ten were unable to answer questionnaires at ICU discharge. Consequently, evaluation at ICU discharge was performed in 45 patients
[b]Two patients died in the hospital after ICU discharge. Consequently, evaluation at hospital discharge was performed in 43 patients
[c]Seven patients lost to follow-up between hospital discharge and day 90 and two were unable to answer questionnaires. Consequently, evaluation at day 90 was performed in 34 patients

(major sources of altered sleep and EEG patterns) [35] had been discontinued for < 24 h. It is also noteworthy that most patients in our study were not intubated at the time of polysomnography, although a substantial proportion of them had previously been intubated (Table 1) and were globally less severely ill than patients in previously published studies. This could explain the absence of atypical sleep recordings, which have been described mostly in critically ill patients [29, 34]. Of note, the intervention was applied from 10:00 p.m. to 8:00 a.m., which can be considered as too long. However, this allowed a little flexibility and guaranteed that patients would receive the intervention for at least 8 h. Sleep recording was performed from 2:00 p.m. to 8:00 a.m. in order to be consistent with most studies on sleep in the ICU. Also, we admit that sleep outside, and particularly before, the intervention is unlikely to be altered by the intervention. For this reason, we report our results for the whole duration of recording and also for nighttime.

The N3 percentage of total sleep time, which was the primary outcome of our study, was not significantly different between the two groups. Total sleep and night sleep times, as well as various descriptors of sleep architecture, were also not significantly different, suggesting that a protective strategy based on the use of earplugs and an eye mask at night does not improve sleep duration or architecture. These results are in contrast with those of previous studies reporting the benefit of this strategy. However, none of these studies were conducted in a general ICU population, and none were based on the use of polysomnography, because the only study that used polysomnography was conducted in healthy subjects subjected to ICU noise and light conditions [36]. In this study, earplugs and an eye mask improved REM sleep time and arousals but failed to improve N3 time, total sleep time, and sleep efficiency. Studies conducted in critically ill patients showed that earplugs and an eye mask were associated with an improvement in score-assessed sleep perception [12, 36, 37] as well as melatonin and cortisol levels [36]. In addition, a recent meta-analysis suggested that the use of earplugs and an eye mask was associated with a significant reduction of the incidence of delirium [38, 39]. None of these studies used polysomnography, and most of them were conducted not in a general ICU but in a postanesthesia care unit [12] or cardiac surgical ICU [36].

A major limitation of our study was that many patients did not wear earplugs and an eye mask all night long. Subsequently, the study was likely to be underpowered to detect a significant difference, as suggested by the increase in N3 stage sleep in the per-protocol analysis. Some patients removed their devices, whereas in others earplugs and the eye mask shifted during the night. The general tolerability of the intervention is a key to its success. Previous studies have shown that many patients found earplugs and even an eye mask uncomfortable or very uncomfortable [40], with compliance averaging 13% [38]. Patients complained about earplugs not staying in place and sore ears or reported feeling anxious when they did not hear any background noise [11, 40, 41]. Patients also complained that eye masks made them feel hot and sweaty and were too tight, causing a feeling of claustrophobia [40]. Consequently, patients may be unwilling to use earplugs or an eye mask [42]. This is all the more true in that patients of the intervention group who wore earplugs only part of night had even poorer sleep quality than patients in the control group. It raises the hypothesis that the poor tolerance of the device altered sleep architecture, possibly because of anxiety and claustrophobia. ICU staff should therefore improve the acceptability of these devices by clearly explaining the potential benefits to the patients, by helping patients to choose the best device in terms of shape and size, and

by providing adequate assistance and instructions concerning their use [36]. Future improvement of the quality of these devices may also help to improve their tolerance.

Another limitation of our study that could have influenced the results was the fairly large proportion of N3 sleep in the control group. With a median of 11% of total sleep time, the proportion of N3 sleep observed in our study exceeded that reported in previous studies [9, 19]. This high proportion of N3 sleep could be consistent with the major efforts undertaken in our unit to improve sleep quality, including, but not limited to, lights turned off at 10:00 p.m. in rooms, televisions turned off at 10:00 p.m., and minimal room alarms. In addition, window blinds are raised during the daytime, and patient mobilization is encouraged in order to promote normal circadian rhythms. All patients are also accommodated in single rooms. Despite these measures, median sound levels were 55 (54–58) dB and 56 (54–57) dB in the control group and intervention group, respectively, with peaks > 70 dB. These levels are higher than those recommended by the World Health Organization (>35 dB) but similar to the noise levels reported in previous studies [43].

However, this protective strategy was associated with a reduction of prolonged awakenings, which suggests that earplugs and an eye mask had at least a minor impact on sleep architecture. It is of note that this is a relevant criterion in term of sleep disturbance and that one could argue that it would have been more logical to select it as the primary outcome because the main purpose of wearing earplugs and an eye mask is to prevent awakening by external stimuli. Nevertheless, in light of our results, it would be unreasonable to expect a single intervention, namely wearing earplugs and an eye mask, to dramatically improve sleep quantity and quality, which depend on multiple and complex determinants. Recently, Kamdar et al. reported the impact of a multifaceted intervention designed to improve sleep quality in ICU patients [8]. Earplugs and an eye mask were part of this strategy, which also included nighttime interventions to reduce sleep disruption at night and daytime interventions to promote a normal circadian rhythm. Although this multifaceted intervention did not significantly improve sleep quality, it did improve the perceived nighttime noise and the incidence of delirium [8]. In addition, although a correlation has been observed between noise level and arousal frequency in ICU patients [44], a questionnaire administered to patients after ICU discharge showed that other human interventions, such as phlebotomy and measurement of vital signs, were even more sleep-disruptive than noise [45]. Noise and care activities could account for < 15–30% of arousals and awakenings in ICU patients [9, 19].

Conclusions

The use of earplugs and eye masks at night in ICU patents who have awoken from the effects of sedation did not increase the N3 proportion of sleep, but it did decrease the number of prolonged awakenings in ICU patients and also increased N3 duration when these devices were well tolerated. Earplugs and an eye mask had no impact on outcome. A major limitation of this study is the limited willingness of patients to use these devices, which were the source of numerous complaints. It seems that the benefit of wearing earplugs and an eye mask is at least partially counteracted by the discomfort of wearing the devices. Because the improvement of sleep quality in ICU patients remains a major concern, future studies should evaluate multifaceted programs, possibly including protective devices, rather than focusing on a single intervention.

Additional files

Additional file 1: Table S1. Additional patient characteristics prior to inclusion. (DOC 30 kb)

Additional file 2: Table S2. Nurse interventions and noise level. (DOC 33 kb)

Additional file 3: Table S3. Main sleep characteristics in patient subgroups according to whether patients wore earplugs all night long. (DOC 33 kb)

Additional file 4: Figure S1. Study flowchart including patients followed at ICU discharge, hospital discharge, and 90 days after inclusion. (DOC 102 kb)

Abbreviations

EEG: Electroencephalography; HADS: Hospital Anxiety and Depression Scale; ICU: Intensive care unit; IES-R: Impact of Event Scale–Revised; RASS: Richmond Agitation-Sedation Scale; REM: Rapid eye movement; SAPS: Simplified Acute Physiology Score; TST: Total sleep time; VAS: Visual analogue scale

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Availability of data and materials

The datasets used and/or analyzed during the present study are available from the corresponding author on reasonable request.

Authors' contributions

AD, TS, and IA designed the study. AD, SC, and SL coordinated the study. AD, SC, SL, EM, and JM were responsible for patient screening, enrollment, and follow-up. AD, SC, OP, IA, TS, and SL analyzed the data. AD, SC, and TS wrote the manuscript. All authors had full access to all study data, contributed to drafting the manuscript or critical revision of it for important intellectual content, approved the final version of the manuscript, and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors read and approved the final manuscript.

Ethics approval and consent to participate
Human research ethics committee approval for the study was provided by the Comité de Protection des Personnes - Ile de France 6. Patients or their next of kin gave informed consent.

Consent for publication
Not applicable.

Competing interests
AD reports receiving personal fees from Maquet; grants, personal fees, and nonfinancial support from Covidien; personal fees from MSD; grants and nonfinancial support from Philips; nonfinancial support from Dräger; grants and personal fees from ResMed; and personal fees from Fisher & Paykel (all outside the submitted work). IA reports receiving personal fees from UCB Pharma outside the submitted work. TS reports receiving personal fees from Almirall France, personal fees from AstraZeneca France and corporate personal fees from Boehringer Ingelheim France, personal fees from GlaxoSmithKline France, personal fees from Invacare, personal fees from Mundipharma, personal fees and nonfinancial support from Novartis France, personal fees from Pfizer France, grants and personal fees from Pierre Fabre Médicaments, personal fees from Takeda, personal fees from Teva Pharma, and personal fees from Lungpacer Medical Inc., all outside the submitted work. The other authors declare that they have no competing interests.

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Effects of Earplugs and Eye Masks on Perceived Quality of Sleep during Night among Patients in Intensive Care Units

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Abstract: ***Sleep disruption is a common problem among ICU patients and causes of sleep disruption are multi factorial. Noise and light are the most common sleep disruptive factors which have negative physiological and psychological effects on patients admitted in ICU. This prospective randomized crossover design study aims to assess the effectiveness of earplugs and eye masks on perceived quality of sleep among patients admitted in intensive care units. Fifty patients from different ICUs of AIIMS, Delhi were randomly allocated into two groups. One group received earplugs and eye masks during first night and only routine environment provided on the second night, while another group did not receive earplugs and eye masks on first night and received on second night. Sleep was assessed in the coming morning by modified Richard Campbell Sleep Questionnaire (RCSQ). Data analysis was done using STATA 11.1, with the level of significance at p < 0.05. There was significant improvement in mean sleep score when earplugs and eye masks (70.26 ± 5.89 and 68.74 ± 6.54) versus routine environment (45.86 ± 4.86 and 43.06 ±7.31) was used (p < 0.01). Noise and light were major sleep disturbing factors among ICU patients, earplugs and eye masks were found to be significantly (p = 0.04) correlated with noise and light. It is concluded that earplugs and eye masks are relatively cheap interventions with notable improvements in quality of sleep and valuable addition to the patients attempting to sleep in an intensive care units. Earplugs and eye masks could be used as an alternative to sleep medications for patients when appropriate.***

Keywords: Earplugs, eye masks, Quality of sleep, Intensive care units, Intensive care unit patients

1. Introduction

Sleep is a natural state of bodily rest. It is common to all irrespective of breed, culture and caste.[1] Regular sleep is essential for survival for human beings. Two physiologic processes regulate sleep, the circadian and homeostatic mechanisms where the homeostatic component monitors the need for sleep and circadian process governs the variations in sleep over 24 hours. [2, 3]

Many physiological, psychological and environmental factors contribute to the incidence of sleep disruption for the ICU patients. The primary physiologic factors documented in the literature are pain, medications and illness (G. L. Weinhouse, R. J, Schwab. 2006). [4] Stress and worry are the primary psychological factors which disrupt sleep. Environmental factors include noise, lights and patient care activities disrupt sleep in ICU settings. Environmental factors and patient care activities can be manipulated to decrease patients' sleep disruption (Freedman, N.S. 1999). [5] Noise can be reduced using simple interventions such as turning down the volume on alarms, closing patient doors and the use of earplugs (Christensen, M. 2005). [6] The use of earplugs to decrease noise disruption should be studied as a way to help improve sleep quality for acutely ill patients in the ICU setting.

In addition, light exposure is another important sleep disruptor. Nocturnal melatonin secretion can be acutely suppressed by light. ICU patients suffer from a severe lack of sleep associated with loss of the nocturnal melatonin secretion pattern during night (Shilo L, Dagan Y, Smorjk Y, Weinberg U, Dolev S, Komptel B. 1999). [7] Therefore, effective interventions like use of eye masks to decrease light exposure and to promote sleep in ICU patients are urgently needed. [8, 9]

The **objective of the study** was: To assess the effectiveness of earplugs and eye masks on quality of sleep among patients admitted in ICUs of AIIMS, New Delhi.

2. Methods and Materials

2.1 Design and Setting

For this study randomized controlled trial (RCT) crossover design was used. Patients admitted in ICU of AIIMS were enrolled. Ethical clearance for the study was obtained from institute Ethics Committee. Data was collected from June to November 2013. 65 patients were screened for the study and 50 patients met the eligibility criteria were randomly allocated to two groups i.e. Group A and Group B using computer generated random table.

2.2 Participant's Eligibility Criteria

Patients admitted in ICUs, conscious, able to communicate in English and Hindi, ICU stay for 2 to 7 days and age 20 – 70 years were enrolled. Patients with ear injury, hearing impairment, eye disease or injuries, phlebitis or cellulitis, contagious skin conditions, eczema and other skin lesions,

patients on mechanical ventilators and taking medications for sleep were excluded.

2.3 Procedure for Data Collection

A letter explaining the purpose of the study was given to the subjects. Signed informed consent was taken from the subjects. Random assignment to either of the two groups was done based on randomization table. Demographic related data was collected by interview technique using questionnaire. Group A received the intervention (earplugs and eye masks) during night from 9 pm to 6 am on the first day and did not receive intervention on second day. Group B did not receive any intervention during night on the first day and received intervention (earplugs and eye masks) on the second day from 9 pm to 6 am. The earplugs and eye masks were selected by reviewing criteria of noise and light reduction as mentioned by the manufacturers, previous research, cost and availability. After comparison of foam earplugs of various companies, PU (Polyurethane) foam earplugs were selected as it has highest noise reduction rating (SNR-37Db) and for single use. Eye masks with silky soft black taffeta inside, outside with cushioned filler and two elasticized straps with nose bridge were selected. Routine environment remained the same on both the days for both the groups. The quality of sleep was assessed in coming morning by using modified Richard Campbell Sleep Questionnaire (RCSQ).

Measures

1) A structured tool including the demographic, clinical data and selected variables was prepared to collect data from subjects using interview technique.
2) A 0 mm to 100 mm visual analogue scale (VAS) developed to assess sleep quality based on Richard Campbell Sleep Questionnaire (RCSQ). Reliability evaluated as 0.82.

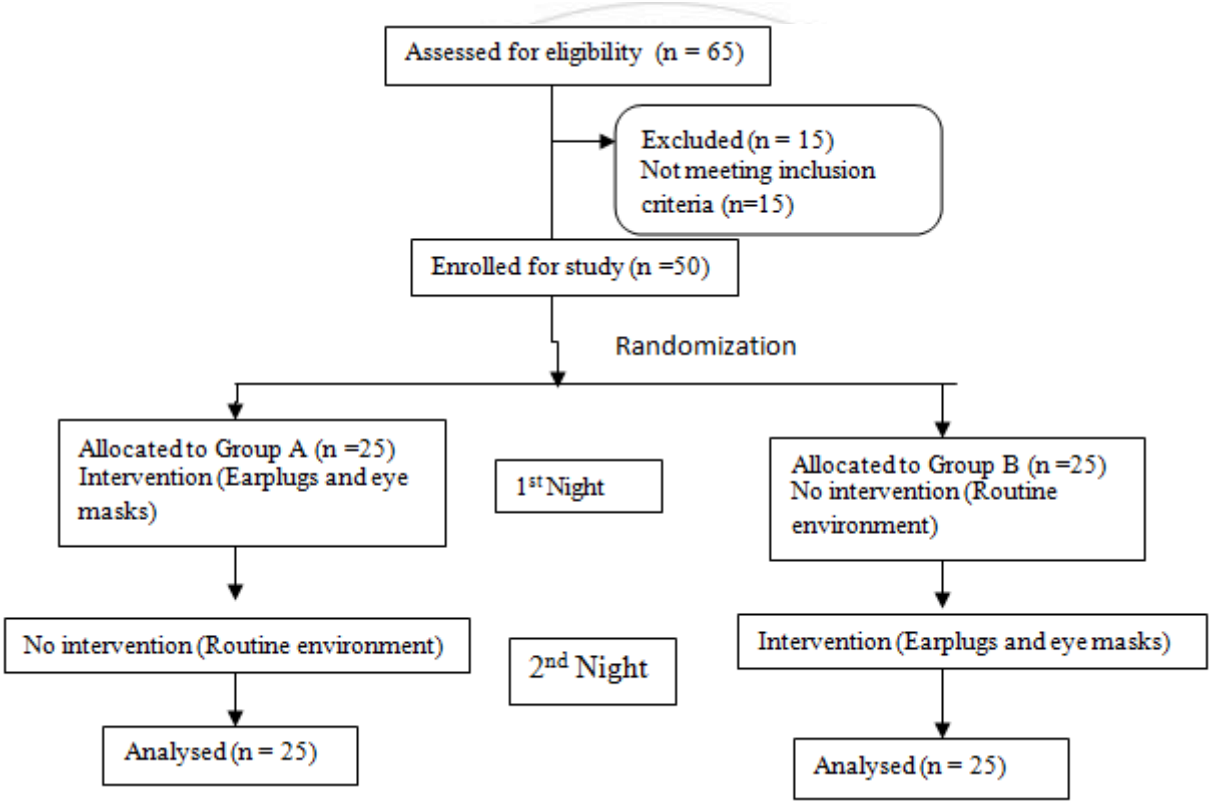

Figure 1: Consort diagram

3. Results

Demographic Characteristics

Mean age of the subjects was 40 years. 84% were male, 68% were married and 47% subjects were educated above 12th standard. 68% were employed out of which 74% were doing day shift duties.78% of the subjects expressed that they did not use any routine assistance to achieve sleep. 94% of the subjects expressed noise, 42% light and 8% pain as sleep disturbing factors in ICU environment. 60% were pre and post operative surgical patients.

Effectiveness of sleep promoting devices (earplugs and eye masks) on sleep quality:

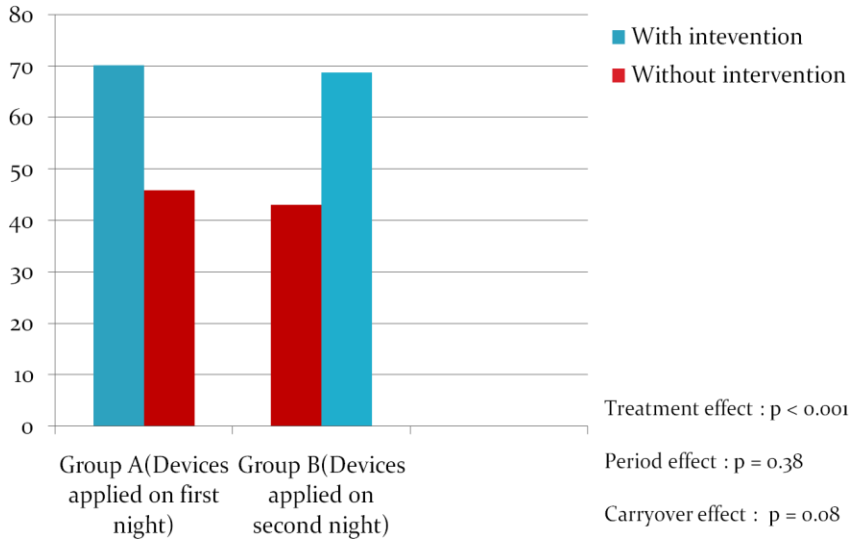

Figure 2: Sleep score (Mean ± SD) with and without intervention in two groups

As shown in figure 2, during first night, the mean sleep score was found to be 70.26 ± 5.89 in group A with intervention (using earplugs and eye masks) and during second night, the mean sleep score in the same group without intervention was found to be 45.86 ± 4.86.

During first night the mean sleep score in group B was found to be 43.06 ± 7.31 without intervention and during second night, the mean sleep score of 68.74 ± 6.54 with intervention (using earplugs and eye masks) among ICU patients. The treatment effect; $p < 0.01$, signifies that, the earplugs and eye masks have highly significant effect in improving quality of sleep among ICU patients. The period effect of $p = 0.389$ and carryover effect, $p = 0.085$ showed that there is no significant effect of the wash out period between the two nights on the quality of sleep of the total subjects. Thus a significance effect on quality of sleep was seen in intervention group as compared to non intervention group at 0.05 levels.

Noise and light were major sleep disturbing factors among ICU patients. Sleep score of subjects who expressed noise and light (70.5 and 69) as sleep disturbing factors were lower than subjects who expressed pain and other factors (61.5 and 73.75) with p value of 0.04.

4. Discussion

Subjective mean sleep score in Group A was found to be 70.26 ± 5.89 with intervention and 45.86 ± 4.86 without intervention. In Group B subjective mean sleep score was found to be 43.06 ± 7.31 without intervention and 68.74 ± 6.54 with intervention among ICU subjects. There was significant improvement ($p < 0.01$) in quality of sleep after intervention as compared to routine environment (no intervention).

The above findings were similar to the study conducted by **Wallace, Robins, Alvord, Walker (1999)** [11] evaluated the effect of earplugs on sleep. This study used a repeated measures cross over design with an average age of 25 +/- 3 years. After one night of adaptation, participants were divided into two groups: the first group wore earplugs and the second group did not. For participants using earplugs, REM latency (time to enter REM sleep) decreased significantly and the use of earplugs significantly increased the percentage of REM sleep.

The results of this study also revealed that noise and light were major sleep disturbing factors among ICU subjects, earplugs and eye masks were found to be significantly ($p = 0.04$) correlated with noise and light.

This study results are supported by **Lane T, East LA (2008)** [9] conducted a study to describe the sleep experience of patients in surgical wards and ICU. According to the study results environmental factors were found to be strongly correlated with sleep disruption with a Pearson's coefficient of + 0.795. This study found that environmental noise, light and tension were the major factors that disrupt the sleep of surgical patients.

This findings also supported by **Koen S Simons, Mark van den, Boogaard, Cornelis PC de (2012)** [10] conducted a study on ICU patients and concluded that for non-ventilated critical care patients noise the combination of earplugs and eye masks were effective to improve sleep. Koen and mark analyzed 18 ICU patients who were offered the choice of wearing earplugs and eye masks from 10 pm to 6 am. In these patients self-perceived quality of sleep improved from 6.6 (5.9 to 8.2) to 7.5 (7.0 to 8.0) ($P = 0.041$) when the earplugs and eye masks were worn.

Additional findings

Besides these results, more than 70% of the subjects in ICUs commented that earplugs and eye masks were comfortable to use and improved their sleep quality as compared to previous nights.

Study limitations

Study involved only ICU subjects, conducted in single setting with small sample size. Objective sleep assessment was not done.

Implications

- Nursing education

Alternative sleep promoting strategies can be incorporated in the curriculum of undergraduate nursing students.

- Nursing practice
  Earplugs and eye masks can be used as an adjuvant therapy to improve the quality of sleep among ICU patients. Nursing care and ward routine should be scheduled in such a way that it should not interfere with patients' sleep.

5. Future Recommendations

A multicentre study with a larger sample size can be undertaken. Studies can be done with earplugs and eye masks separately. Earplugs and eye masks can be applied for more than one night (From admission to discharge). Effectiveness of earplugs and eye masks may be assessed in other clinical areas of hospital. Objective measurement can be done like nocturnal melatonin and cortisol to evaluate the effectiveness of earplugs and eye masks on sleep quality.

6. Conclusion

Based on the findings of the present study it is concluded that the quality of sleep was improved after application of earplugs and eye masks among ICU patients. From the above results, it appears that simple interventions such as earplugs and eye masks may be a valuable addition to patients attempting to sleep in intensive care units. Earplugs and eye masks could be used as an acceptable sleep intervention and alternative to sleep medications for patients when appropriate.

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ORIGINAL RESEARCH PAPER

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Effectiveness of using eye mask and earplugs on sleep length and quality among intensive care patients: A quasi-experimental study

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Abstract

Aim: This study aims to assess the effect of using a combination of eye mask and earplugs on the perceived quality of sleep among patients admitted to intensive care units.

Design: Control group, pretest and posttest, quasi-experimental design was used.

Methods: Data were collected from 103 intensive care patients in two governmental hospitals in Jordan. The participants were assigned either an experimental or a control group. The experimental group participants received routine care in the first night and used the eye mask and earplug during their sleep in the second night. Control group participants, on the other hand, received routine care only in both nights. The number of hours slept was reported by nurses, and the perceived quality of sleep was self-reported by participants using the Richards-Campbell Sleep Scale.

Results: Experimental group participants slept more hours and reported significantly better perceived quality of sleep after the use of eye mask and earplugs, as compared both with themselves in the first night and with control group participants.

Conclusion: Combining eye masks and earplugs is effective in prolonging the sleep of intensive care patients and improving its quality.

KEYWORDS

earplugs, eye mask, ICU patients, patients' quality of sleep

SUMMARY STATEMENT

What is already known about this topic?

- Many strategies were tested and adopted in intensive care units (ICUs) worldwide in order to improve patients' sleep quality, but evidence of these strategies' effectiveness was scarce.
- Combining the use of eye mask and earplug has shown positive results on sleep length and quality in ICUs in a number of countries.

What this paper adds?

- This study is the first one of its kind in Jordan and in the Arab world.
- This study combines the subjective self-reported quality of sleep with objective length of sleep as assessed by nurses.

The implications of this paper:

- This paper's findings will inform nursing practice in the ICUs in Jordan in terms of patient's sleep improvement strategies.
- This paper will inform policymaking and future research in the field of ICU patients' sleep length and quality.

1 | INTRODUCTION

Poor quality of sleep is common among the intensive care unit (ICU) patients (Tembo, Parker, & Higgins, 2013; Wang & Greenberg, 2013). The ICU patients might have normal total sleep time, but they frequently report a decrease in the slow waves and rapid eye movement (REM) sleep that might result in frequent arousals (Elliott, McKinley, Cistulli, & Fien, 2013). Research studies found that more than 50% of the ICU patients have sleep disturbances (Walder, Haase, & Rundshagen, 2007).

Although sleep is an obvious problem in the ICU (Talwar, Liman, Greenberg, Feinsilver, & Vijayan, 2008), it was not given great attention by nurses as a priority (Wang & Greenberg, 2013). Although several previous studies have suggested poor quality of sleep among the ICU patients and despite the importance of the problem, few clinical studies worldwide have investigated the impact of interventional programs or strategies on the patients' sleep quality (Gay, 2010; Weinhouse & Schwab, 2006).

1.1 | Background

In the past two decades, various strategies were tested and utilized in different countries in order to improve ICU patients' sleep quality (Hu, Hegadoren, Wang, & Jiang, 2016). These strategies included noise reduction, lighting control, relaxation technique, meditation, hypnosis, earplug, eye masks, soft music, and nursing care provision timing modification. However, evidence of success of many of these strategies is scarce, and nurses' attitude toward the issue remains below expected (Abolhasani, 2006; Aitken et al., 2017; Tamrat, Huynh-Le, & Goyal, 2013).

The use of eye masks and earplugs is a promising strategy in managing sleep disturbances in the ICU. This was evident in several studies. In their study, Le Guen, Nicolas-Robin, Lebard, Arnulf, and Langeron (2014) simulated ICU environment on healthy persons and examined the influence of this strategy on their sleep quality. The results showed that the use of earplugs in combination with eye masks improved melatonin secretion, improved REM sleep, reduced REM sleep latency, and reduced arousals indices.

To evaluate the effects of using earplugs and eye masks accompanied with relaxing music on sleep quality, melatonin, and cortisol levels in ICU patients, an important study was conducted by Fang Hu, Jiang, Hegadoren, and Zhang (2015). The results showed a significant difference between the experimental and control groups in terms of depth of sleep, falling asleep, awakenings, falling asleep again after awakening, and overall sleep quality ($P < .05$). The perceived sleep quality was better in the experimental group.

1.2 | Significance

To the best of our knowledge and after searching the Jordanian Database for Nursing Research (JDNR) and research databases of CINAHL, MEDLINE, and Google Scholar, no clinical trials have been conducted in Jordan to evaluate the influence of using the eye mask and earplugs on the patients' quality of sleep to date. Therefore, this experimental study is the first one in Jordan to examine this influence. The general purpose of this experimental study is to investigate the effect of using eye mask and earplugs on the quality of sleep among ICU patients.

Thus, testing the strategy of combining the use of eye masks and earplugs in a sample of ICU patients in Jordan may inform future policy, nursing practices, and further research. Health care providers in Jordan, specifically nurses, may find this study greatly important as it informs their effort to provide optimal care and comfort to their patients in the ICUs in Jordan and the surrounding Arab countries. It is however important to state that ICU patients who are on sedation and mechanically ventilated, whose CVS is unstable, or who use sleeping bills are beyond the generalizability of this study's findings, as they are excluded from the sample. Furthermore, the findings of this study can support the decision-making of hospital administrators in terms of investing in the supplies of earplugs and eye masks if they are found to have a significant positive influence on ICU patients' sleep quality and, ultimately, on the hospitalization experience in general.

1.3 | Research hypothesis

H_A: Participants of the experimental group, where a combination of eye masks and earplugs are used, will report better quality of sleep than subjects in the control group, where routine care is provided.

2 | METHODOLOGY

2.1 | Design

A control group, pretest and posttest, quasi-experimental design was used in this study. This design includes collecting data before and after the implementation of an intervention from experimental group participants and control group participants.

2.2 | Sample and sampling

The target population for this study was all Jordanian ICU patients, while the accessible population was the ICU patients at Princess Basma Teaching Hospital and Ma'an Governmental Hospital. A consecutive sampling procedure was used to select the participants in this study. The total sample size needed for this study was 102 participants. This number was determined based on the G power statistical software program (G power version 3.1.9.2), using independent samples t test, with a medium effect size (Cohen $d = 0.5$), significance α level of .05, and power size of .8.

As shown in Figure 1, 103 patients who were admitted to the ICU at Princess Basma Teaching Hospital and Maan Governmental Hospital during February, March, and April 2017 and who agreed to participate in the study were recruited and completed this study. The inclusion criteria for participating in this study were obtained from the patients' files and interviews. It includes (a) patients who are at

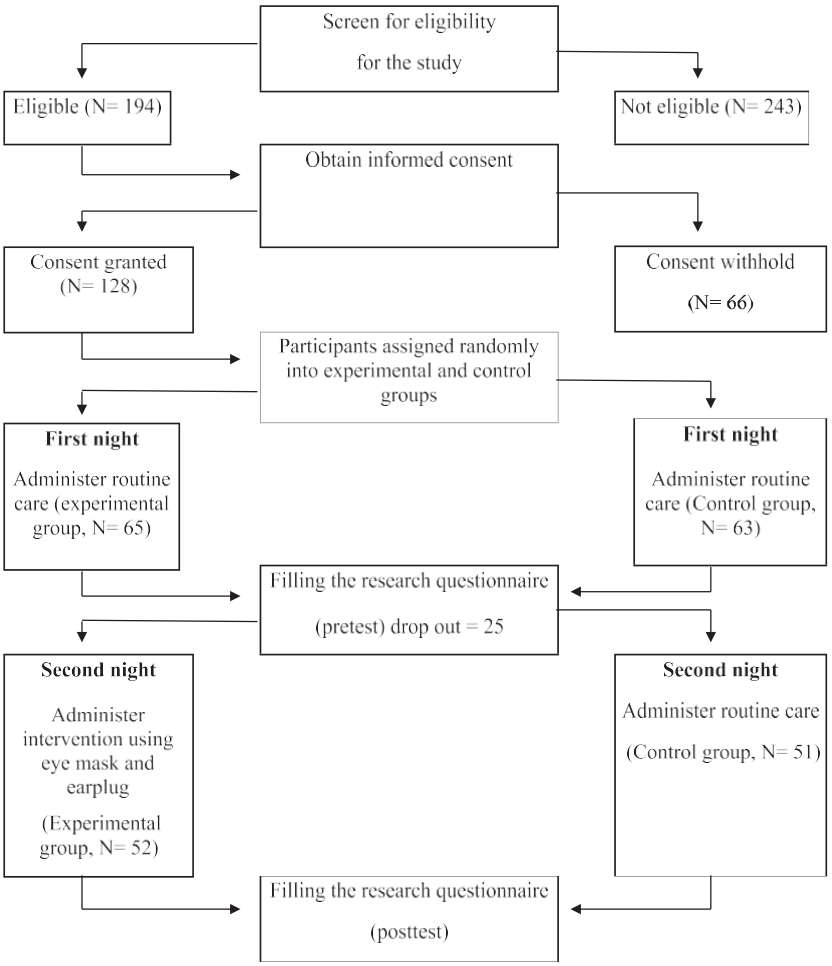

FIGURE 1 Sampling and intervention

least 18 years of age; (b) has Glasgow coma score (GCS) of more than 12 in the first and second nights in which data were collected; (c) able to hear, write, and speak Arabic language, since the research questionnaire was administered to the participants in Arabic language; (d) haemodynamically stable with normal vital signs; and (e) able to provide consent to participate in the study. The participants were excluded from the study in the following cases: (a) patients who use sleeping pills or who were administered any form of sedation, (b) patients who were mechanically ventilated, (c) patients with brain damage or any other neurological problems, (d) patients with psychiatric disorders, (e) patients with chronic sleep problems, (f) patients with hearing problems requiring the use of hearing aids, and (e) patients who were blind. Finally, the participants' participation in the study was terminated in the following cases: patients' transfer to other units or other hospitals before sleeping the second night in the ICU, patients' discharge from the hospital, patients' request to quit their participation, or the worsening of the patients' conditions.

2.3 | Ethical considerations

Permission to conduct this study was obtained from the Scientific Research Committee in the School of Nursing at University of Jordan, University of Jordan Ethical Committee, and IRB committee at the Ministry of Health.

All ethical principles including the respect of person's rights, beneficence, justice, privacy, and confidentiality of the participants' information were applied. Written and verbal informed consents from the participants were obtained at the beginning of the study and before the implementation of the intervention. The participants were informed that they are free to refuse to participate or withdraw from the study at any time.

2.4 | Setting

This study was conducted in two multidisciplinary ICUs at two large governmental educational hospitals in Jordan. The first setting is the ICU at Princess Basma Teaching Hospital in Irbid city. This hospital is the largest governmental hospital in the north region that serves more than one million residents. The bed capacity of this hospital is 230, and the ICU capacity is 12. The second setting is the ICU at Ma'an Governmental Hospital, which is considered as one of the largest hospitals in the south region of Jordan. The bed capacity of this hospital is 151, and the ICU capacity is 13. The ICUs at both hospitals are open multidisciplinary that receive medical and surgical patients with severe illnesses. The average stay of the patients in these units is about 5 to 6 days.

2.5 | Procedure of intervention and data collection

The research intervention including the use of eye mask and earplugs was performed over one night for each participant in the experimental group. Collecting data about the inclusion and exclusion criteria, demographical data, quality of sleep in the first night, and quality of sleep in the second night was performed by the researchers themselves.

2.5.1 | First day

In the first day of data collection for each participant, the researcher explained to the eligible patients the purpose behind conducting this study and the steps of the intervention. The patients who agreed to participate in the study were asked to sign the consent form and were assigned randomly to the experimental or control groups using simple randomization technique. The patients with files of odd numbers were assigned to the control group, while the patients with even numbers were assigned to the experimental group.

2.5.2 | First night

In each first night of data collection, the participants in the experimental and control groups were asked to sleep at any time between 10 PM and 12 AM without using the eye mask and earplugs. They received the routine nursing care, which includes dimming the lights and minimizing noise at night.

2.5.3 | Second day

In each second day of data collection, all participants in both groups were asked to fill the pretest research questionnaire (Richards-Campbell Sleep Scale [RCSS]) about the patients' quality of sleep in the first night, and the number of hours slept that night was collected by nurses.

2.5.4 | Second night

In each second night of data collection, the participants in the experimental group were taught about how to use the eye mask and earplugs. The participants in the control group were asked to sleep at any time between 10 PM and 12 AM, and they received routine nursing care, which includes dimming the lights and minimizing noise at night, and the number of hours slept that night was collected by nurses. The participants in the experimental group were asked to sleep at any time between 10 PM and 12 AM, and they received routine nursing care in combination with the use of eye mask and earplugs from 10 PM to 6 AM.

2.5.5 | Third day

In the third day of data collection for each participant, the researcher filled the demographic part of the posttest questionnaire, and all participants in both groups were asked to fill the posttest research questionnaire (RCSS), and the number of hours slept that night was collected by nurses. This process was frequently repeated until the required sample size was achieved.

2.6 | Instruments

A self-reported questionnaire was used in this study. It includes two parts: pretest and posttest. The pretest part includes demographic survey of the participants, RCSS, and the number of hours slept. The posttest part includes RCSS and the number of hours slept.

2.6.1 | Demographic survey

The part of demographic data was developed by the researcher in Arabic to collect information about the age, gender, educational level, marital status, educational level, medical diagnosis, the length of stay in the ICU at the time of data collection, medical history of other diseases, and the history of previous hospital admission.

2.6.2 | Richards-Campbell Sleep Scale

RCSS is a scale that was used in this study to measure the patients' quality of sleep in the critical care units. The RCSS was validated against polysomnography recordings in an Medical Intensive Care Unit (MICU) population. The tool is composed of five items with a 100-mm visual analogue scale. It measures the perceived depth of sleep, sleep latency (time spent to fall asleep), number of awakenings, returning to sleep after wakening, and sleep quality. The overall mean score of the five items was considered the score that represent the patients' perception of the overall quality of sleep. The psychometric properties of this tool were tested in several studies. For example, in a study conducted by Li, Wang, Wu, Liang, and Tung (2011), Cronbach alpha coefficient was .90, and there was a moderate correlation between the polysomnography and the RCSS in measuring the quality and depth of sleep (r = .59). However, Cronbach alpha for the six subdomains in the current study was .927.

Double translation (translation and back translation) involving the use of two translators who were working independently was used. The scale was translated from its original English language into the Arabic language. Then it was translated back into the English language by another translator who is unfamiliar with the original scale.

2.7 | Statistical analysis

Data were analysed using Statistical Package for the Social Sciences (SPSS, version 21, Chicago Inc) program. Prior to conducting data analysis, preliminary data screening and cleaning of outliers, missing values, and skewness were performed. All assumptions for all statistical analysis were tested considering the level of measurement for all variables. Descriptive analysis, visual inspection of histograms, scatter plots, skewness, and kurtosis were tested to ensure the accuracy and to assess the normality of the continuous variables. Inferential

statistics was used to test hypotheses. To test the hypothesis, independent samples *t* test was used. The similarity in the sample characteristics between the experimental and control groups was ensured by conducting the independent samples *t* test and chi-square test. This was done to exclude any significant possible effect of the demographic variables on the patients' quality of sleep. The level of confidence was defined at .95.

An effect size calculation (Cohen *d*) for the difference in the means of perceived quality of sleep before and after the use of eye mask and earplugs will be done based on Cohen criteria (1988), where a Cohen *d* value of 0.2 is identified as small effect, a *d* value of 0.5 is a medium effect, and a *d* value of 0.8 is a large effect.

3 | RESULTS

3.1 | Similarity between experimental and control group members

As shown in Table 1, the demographic variables did not differ significantly between the two groups.

3.2 | Testing of hypothesis

To test the study hypothesis, independent samples *t* test was performed. The results indicated that there were significant differences in all aspects of sleep quality. The *t* value for the overall quality of sleep was statistically significant, $t_{101} = 3.48$, $P = .001$, two-tailed. The overall mean of the perceived quality of sleep for the participants in the experimental group (M = 47.20, SD = 16.52) was approximately (10.91) more than the overall mean of the perceived quality of sleep for the participants in the control group (M = 36.29, SD = 15.10). Table 2 shows a comparison between the patients' quality of sleep in the experimental and control groups (posttest).

To ensure that the significant difference in the quality of sleep between the participants in the experimental and control groups is related to the use of eye masks and earplugs and not related to pre-existing differences, initial independent samples *t* test was performed before the use of eye masks and earplugs. The results indicated that there was no significant difference in the overall mean of the perceived quality of sleep for the participants in the experimental and control groups, $t_{101} = -0.158$, $P = .88$, two-tailed. The overall mean of the perceived quality of sleep for the participants in the

TABLE 1 Comparison of selected characteristics for the participants in the experimental and control groups (*N* = 103)

Item	Category	Experimental Group	Control Group	*t* Test	*P*
		Mean (SD)	Mean (SD)		
Age	(years)	51.18 (18.67)	56.18 (18.56)	1.358	.177
Length of Stay in the ICU at the time of intervention	(days)	2.52	2.53	−0.046	.963
		Frequency	Percentage		
Sex	Male	30	34		.348
	Female	22	17		
Marital status	Single	3	4		.747
	Married	42	42		
	Divorced	1	0		
	Widow	6	5		
Educational level	Less than high school	20	25		.749
	High school	14	11		
	Diploma or bachelor	16	13		
	Master or doctoral	2	2		
Medical diagnosis	Cardiovascular	26	24		.398
	Respiratory	7	11		
	Endocrine	1	4		
	Musculoskeletal	1	0		
	Digestive	8	4		
	Others	9	8		
Comorbidities	Cardiovascular	25	18		.334
	Respiratory	0	2		
	Endocrine	11	17		
	Digestive	2	2		
	Others	14	12		
Previous hospitalization	Yes	29	35		.179
	No	23	16		
Treatment with narcotic analgesics	Yes	8	4		.233
	No	44	47		

Abbreviations: *N*, number; SD, standard deviation.

TABLE 2 Comparison between the patients' quality of sleep in the experimental and control groups

Item	Exp. Group		Control Group			P
	Mean	SD	Mean	SD	t	Value
Pretest						
Sleep depth	33.56	12.53	34.71	13.13	−0.45	.85
Sleep latency	34.52	18.39	33.53	15.07	0.29	.77
Awakening	35.77	18.10	37.65	17.18	−0.54	.59
Returning to sleep	34.90	16.40	34.31	14.03	0.19	.85
Sleep quality	36.54	16.04	37.94	14.87	−0.46	.65
Overall quality of sleep	35.29	13.63	35.70	13.13	−0.15	.88
Number of sleep hours	3.54	1.10	3.68	1.33	−0.61	.54
Posttest						
Sleep depth	45.92	17.16	33.82	12.80	4.04	<.001*
Sleep latency	45.90	19.43	35.20	15.68	3.07	.003*
Awakening	47.12	18.61	35.98	18.38	3.05	.003*
Returning to sleep	46.44	18.05	36.18	16.90	2.97	.004*
Sleep quality	50.48	16.92	40.69	17.60	2.88	.005*
Overall quality of sleep	47.20	16.52	36.29	15.10	3.48	.001*
Number of sleep hours	4.87	1.23	3.98	1.42	3.37	.001*

Abbreviation: AD, standard deviation.

*Significant at *a* level of .05 (two-tailed test).

TABLE 3 Comparison of quality of sleep before and after the use of eye mask and earplugs

Item	Pretest	Posttest		P	Effect
	Mean (SD)	Mean (SD)	t	Value	Size
Experimental group					
Sleep depth	33.56 (12.5)	45.92 (17.16)	−5.451	<.001*	0.82
Sleep latency	34.52 (18.4)	45.9 (19.4)	−4.917	<.001*	0.60
Awakening	35.77 (18.1)	47.12 (18.6)	−3.891	<.001*	0.62
Returning to sleep	34.9 (16.4)	46.44 (18.1)	−4.643	<.001*	0.67
Sleep quality	36.54 (16.0)	50.48 (16.9)	−5.578	<.001*	0.85
Overall quality of sleep	35.29 (13.6)	47.2 (16.5)	−5.611	<.001*	0.78
Number of sleep hours	3.54 (1.1)	4.87 (1.2)	−7.393	<.001*	0.11
Control group					
Sleep depth	35.29 (14.0)	33.82 (12.8)	0.791	.433	0.127
Sleep latency	33.53 (15.0)	35.2 (15.7)	−0.692	.492	0.108
Awakening	37.65 (17.2)	35.98 (18.4)	0.639	.526	0.093
Returning to sleep	34.31 (14.0)	36.18 (16.9)	−0.679	.500	0.120
Sleep quality	37.94 (14.9)	40.69 (17.6)	−1.126	.266	0.168
Overall quality of sleep	35.70 (13.1)	36.29 (15.1)	−0.282	.779	0.041
Number of sleep hours	3.68 (1.33)	3.98 (1.42)	−1.527	.133	0.218

Abbreviation: SD, standard deviation.

*Significant at *a* level of .05 (two-tailed test).

experimental group (M = 35.29, SD = 13.63) was approximately similar to overall mean of the perceived quality of sleep for the participants in the control group (M = 35.70, SD = 13.13). Also, there were no significant differences in the means of sleep depth, sleep latency, awakening from sleep, returning to sleep, sleep quality, and the number of sleep hours. Table 2 shows a comparison between the patients' quality of sleep in the experimental and control groups (pretest).

3.3 | Quality of sleep before and after the intervention for the experimental group

To evaluate the patients' quality of sleep before and after the implementation of the intervention, a paired samples *t* test was performed. The results indicated that there is a significant difference in the overall mean of quality of sleep before and after the use of eye mask and earplugs. The *t* value is $t_{51} = -5.61$, $P < .001$, two-tailed. The overall mean of the perceived quality of sleep after the use of eye mask and earplugs (M = 47.2, SD = 16.5) was approximately (11.91) more than the overall mean of the perceived quality of sleep before the use of eye mask and earplugs (M = 35.29, SD = 13.6). All aspects of sleep quality including sleep depth, sleep latency, awakening, returning to sleep after awakening, and sleep quality were significantly improved (Table 3). The effect size (Cohen *d*) for the difference in the means of perceived quality of sleep before and after the use of eye mask and earplugs was equivalent to 0.78. Therefore, and according to Cohen (1988) criteria, the effect of using eye mask and earplugs on the perceived quality of sleep is large.

3.4 | Quality of sleep before and after the intervention for the control group

Additional paired samples *t* test was used to assess if there is a difference in the pretest and posttest mean of quality of sleep for the participants in the control group. Preliminary data screening was performed, and the researcher ensured that all assumptions of the paired samples *t* test were met. The results of this test indicated that there was no significant difference in the pretest and posttest overall mean quality of sleep. The *t* value is $t_{50} = -0.28$, $P = .78$, two-tailed. The overall mean of the perceived quality of sleep in the posttest (M = 36.29, SD = 15.1) was (0.59) more than the overall mean of the perceived quality of sleep in the pretest (M = 35.70, SD = 13.1), which indicates approximately equal means. Additionally, no significant improvement in any aspect of sleep was seen (Table 3).

4 | DISCUSSION

The length and quality of patients' sleep in the ICU are essential for health and treatment progress. Sleep disturbances were found in almost all ICU settings including the surgical, medical, and cardiac ICUs (Wang & Greenberg, 2013). In line with the results of the previous studies, we found that the overall means of the patients' quality of sleep before the implementation of the intervention in the experimental and control groups were approximately equal and low (M = 35.29 in the experimental group and M = 35.70 in the control group). This indicates that the patients' sleep in the ICUs in both groups is inadequate in terms of the amount and depth. This result was supported by results of studies conducted by Elliott et al. (2013), and Ritmala-Castren, Lakanmaa, Virtanen, and Leino-Kilpi (2014).

The need for sleep differs in the different ages. In the current study, the pretest average of sleep was 3.54 hours in the experimental group and 3.68 hours in the control group. This amount of sleep is not sufficient and less than the normal sleep in adults (8 h per night). Stuart (2013) stated that most adult persons sleep 6 to 9 hours and the middle-age adults require usually from 7 to 9 hours of sleep per night (Timby, 2005). However, sleep need is determined by the individual sleep requirement to feel alert and demonstrate a peak level of performance during awakening (Mattice, Brooks, & Lee-Chiong, 2012). Therefore, the patients in this study in both groups demonstrated lack of sleep, which might be attributed to the strange environment and to the physiological and psychological stresses caused by their severe illnesses.

Sufficient sleep is a required condition for patients' improvement after severe illness (Fang Hu et al., 2015). Therefore, this result showed the need for developing effective strategies to improve the patients' sleep in the ICU. However, the results of the independent samples *t* test indicated that there was no significant difference in the overall quality of sleep between the two groups, $t_{101} = -0.158$, $P = .88$, two-tailed. This result revealed that the two groups did not vary significantly in demographic characteristics.

Management of sleep disturbance in the ICU might be done by pharmacological and or nonpharmacological methods. Using sleep drugs is the most common method in managing sleep disturbance, but they have several side effects. The use of nonpharmacological methods is safe and might be done with the use of sleep drugs as a complementary intervention (Afshar, Bahramnezhad, Asgari, & Shir, 2016).

As a matter of fact, several strategies might be used to reduce the light and noise levels in the ICU and subsequently improve the patients' quality of sleep. However, the ideal strategy should be feasible, economical, and with no adverse effects (Huang et al., 2014) and that might be achieved by the use of earplugs and eye mask.

The results of the paired samples *t* test after the use of the eye mask and earplugs in the current study showed that the participants in the experimental group have reported better quality of sleep (M = 47.20 in the posttest and M = 35.29 in the pretest). This result is supported by the results of previous studies. Healthy persons who used eye mask and earplugs in a simulated ICU environment reported an improvement in REM sleep, reduction in arousal times, and elevation in the melatonin level (Hu, Jiang, Hegadoren, & Zhang, 2015).

The interpretation of the improvement in the patients' quality of sleep after the use of the eye mask on the patients' sleep arises from the mechanism of the circadian rhythm. When a patient's brain perceives light during the night-time, it directly affects the dark-light cycle. The patient's brain perceives the light as daytime. The patient's biological clock then sends signals to the pineal gland to stop the secretion of the melatonin hormone. When the patient uses the eye mask, it provides darkness, and consequently, the patient's brain perceived this darkness as night-time and sends orders to pineal gland to increase its production of melatonin hormone, which allow the patient to enter in and maintain a sleep. On the other hand, the use of earplugs decreases the patient's perception of sounds by 32 dB, which consequently reduces the patient arousal from sleep.

The results of the paired samples *t* test for the participants in the control group revealed no significant difference was found in the pretest and posttest mean quality of sleep $t_{50} = -0.282$, $P = .78$. Furthermore, no significant differences were found in all aspects of sleep quality. On the other hand, the posttest of independent samples *t* test revealed a significant difference between both groups in terms of sleep depth, sleep latency, awakenings from sleep, returning to sleep after awakening, number of sleep hours, and overall quality of sleep ($P < .01$). The overall perceived quality of sleep in the experimental group was better than the overall perceived quality of sleep in the control group.

Although there was a significant improvement in the participants' quality of sleep in the experimental group after the use of eye mask and earplugs, the overall posttest mean quality of sleep for these participants is still low (M = 47.20). This revealed that the patients' sleep in the ICU was compromised and not efficient even after the use of the eye mask and earplugs. Therefore, this creates the need for the use of other nonpharmacological strategies in combination with the use of earplugs and eye mask to get better quality of sleep.

As long as the participants in both groups have similar demographic characteristics and have been exposed to the same environment, the results of all previous statistical tests might provide evidence that the improvement in the posttest perceived quality of sleep in the experimental group is attributed to the use of eye mask and earplugs and not to effects of other factors.

4.1 | Limitations of the study

This study has some limitations that should be noticed. First, the participants in this study were recruited from only two ICU settings in two governmental hospitals. This was done because data were collected by the researchers themselves and due to time limitation. Another limitation for this study is the use of self-reported questionnaire (RCSS) to measure the patients' perceived quality of sleep. Thus, these findings are limited by the very restrictive criteria applied, in terms of ICU patients. It should not be assumed that the findings will be similar from broader. More representative samples of ICU patients and further studies will be needed to test this.

Some participants found it difficult to fill this scale, and in this case, the scale was filled by the researchers based on the participants' responses. However, this scale was validated against the polysomnography. The technical difficulties, cost, and time limitations are the reasons behind the use of RCSS instead of polysomnography in this study. The evaluation of the patients' sleep only during the night-time is another limitation of this study. Daytime sleep in the ICU comprises a considerable portion from the total sleep time. It might be more helpful when evaluating the patients' quality of sleep during the night-time and daytime.

5 | CONCLUSION

There are strong evidences that the ICU patients have poor quality of sleep. This indicates the need for creating strategies and guidelines for improving the ICU patients' sleep quality. The overall results of this study revealed significant improvement in the participants' perceived quality of sleep using a combination of eye mask and earplugs. Also, the experimental group participants have reported a significantly better quality of sleep compared with the control group participants. Therefore, the researchers conclude that the use of eye mask and earplugs is effective in improving the patients' quality of sleep in the ICUs. Health care providers and administrators in Jordan and beyond are, thus, invited to benefit from these findings in planning future practices inside the ICU. However, further studies are needed to emphasize the results of this study and widen their generalizability.

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CONFLICT OF INTEREST

The authors disclose that they have no conflict of interest to declare.

AUTHORSHIP STATEMENT

MBY and FH contributed to study conception, design, data analysis, drafting and revising the manuscript. HA contributed to data analysis, drafting and revising the manuscript.

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