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Evaluating the effects of earplug placement intervention on sleep quality in patients in an intensive care unit

Submission date
19/01/2020

Recruitment status
No longer recruiting

Registration date
22/01/2020

Overall study status
Completed

Last Edited
21/01/2020

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients in the intensive care unit (ICU) commonly encounter sleep impaired by noise, light, treatments, nursing activities, and other factors, which jeopardizes their recovery. Nonpharmacological interventions have been applied in ICUs to establish a supportive sleep environment; however, the effectiveness of these interventions is uncertain. More rigorous studies with objective measures of outcome parameters are needed. The aim of the study is to evaluate the effects of an intervention involving earplug placement during nocturnal sleep in ICU patients without ventilators.

Who can participate?
Patients aged < 20 years, conscious, able to read and communicate, and have a stay in the ICU that was expected to be more than 48hours.

What does the study involve?
Participants were randomly allocated to use earplugs or not during the hours of 10pm and 7am on the second night of their stay in the ICU.

What are the possible benefits and risks of participating?
Patients have the chance to help the development of scientific knowledge by contributing to the study. Patients in the intervention group might not feel comfortable due to the earplug placement. However, there are no life-threatening side effects to the earplug placement.

Where is the study run from?
Tzu Chi University (Hualien Tzu Chi General Hospital), Taiwan R.O.C.

When is the study starting and how long is it expected to run for?
April 2017 to December 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Hui-Ling Lai
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRB105-119-A

Study information

Scientific Title
Evaluating the effects of an evidence-based earplug placement intervention on sleep quality in patients in an intensive care unit

Study objectives
There will be a difference in the slopes of regression lines for the outcome parameters between those who use earplugs at bedtime and those who do not

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/01/2017, Research Ethics Committee of Hualien Tzu Chi General Hospital (No. 707, Section 3, Zhongyang Rd., Hualien, 97004, Taiwan R.O.C.; +886-3-8561825 ext. 13271; IRB@tzuchi.com.tw), ref: IRB105-119-A

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sleep disturbance

Interventions
A single-center randomized controlled trial was conducted to evaluate the effectiveness of earplug placement alone on perceived sleep quality, urinary melatonin level, and relaxation responses including respiratory rate, heart rate, and MAP in ICU patients. The experimental group received an earplug intervention, and the control group received usual care. Participants' vital signs were recorded continuously during the ICU stay. Earplug administration and urine collection were between 10 pm and 7 am.

On the admission day, all participants were asked to recall their sleep conditions at home prior to admission (Day 0) by using the RCSQ. After baseline data were collected, participants were instructed to draw a random lot from an opaque jar that had 110 lots to determine which group they would be assigned to. Thus, the researchers were blinded to the randomization. Upon admission day following enrollment, a researcher attached physiologic monitors to each participant. The monitors continuously monitored vital signs during the ICU stay.

On the first and second night after enrollment, the frequency of nursing activities occurring between 10 pm and 7 am was recorded every hour on the nursing activity checklist by patients' primary RN. On the second and third day at 10 am, the researcher asked the patients to answer the RCSQ questions. Each item was read aloud by the author (YC) to the patients. The answers were indicated by the patients' writing or by the author.

The research intervention was the use of earplugs. The intervention was delivered on Day2 between 10 pm and 7 am. The earplugs used in the study were disposable polyurethane foam earplugs with a push-in, bell shape feature that matches the contours of the inner ear to protect

hearing, with a maximum noise reduction of 33 dB (MAX-30, Howard Leight). The earplugs were selected and placed by the first author at nocturnal sleep time. Participants in the control group received the usual care.

Patients were informed that if they did not want to continue wearing the earplugs, then they were free to remove them. Immediately after completing the study, participants in the intervention group were asked to describe their feeling regarding the use of earplugs. The control group was only provided with regular care. Vital signs were recorded every 30 min between 10 pm and 7 am on Day 2 and Day 3.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Earplugs

Primary outcome measure
1. Sleep quality measured using the Chinese version of the Richards–Campbell Sleep Questionnaire (RCSQ) at home prior to admission,
at Day 1 (baseline), and at Day 2 (after the intervention)
2. Urinary melatonin (MT6s) level measured using liquid chromatography-mass spectrometry (LC-MS; ACQUITY QDa, Waters Corp. MA, USA) at Day 1 (baseline), and at Day 2 between 10 pm and 7 am
3. Vital signs measured using a physiologic monitor (GE CARESCAPE Central Station, MA, USA), continuously measured during the ICU stay. The values of the vital signs were retrieved at 30-min intervals during the intervention night:
3.1. Respiratory rate
3.2. Heart rate
3.3. Mean arterial pressure (MAP)

Secondary outcome measures
N/A

Overall study start date
01/01/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged < 20 years
2. Conscious
3. Able to read and communicate
4. Have a stay in the ICU that was expected to be more than 48h

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
107

Total final enrolment
107

Key exclusion criteria
1. Use of sedatives
2. Cognitive or hearing impairment
3. Mechanical ventilation or physical restraints

Date of first enrolment
04/04/2017

Date of final enrolment
20/10/2018

Locations

Countries of recruitment
Taiwan

Study participating centre
Tzu Chi University (Hualien Tzu Chi General Hospital)
No. 707, Section 3, Zhongyang Rd.
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Sponsor information

Organisation
Hualien Tzu Chi Medical Center

Sponsor details

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Sponsor type
Hospital/treatment centre

Website
https://bioit.trc.ibms.sinica.edu.tw/hualien-irb

ROR
https://ror.org/030k6vb67

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The study results will be submitted to a nursing journal.

Intention to publish date
15/04/2020

Individual participant data (IPD) sharing plan
The datasets used and/or analyzed during the present study are available upon request from Hui-Ling Lai (snowjade@mail.tcu.edu.tw)
on scientific uses immediately following publication with end date 31/12/2023.

IPD sharing plan summary
Available on request