ISRCTN15393303 https://doi.org/10.1186/ISRCTN15393303

Can providing quiet time, ear plugs, eye masks and reducing noise and light in general medical wards improve the quality of sleep for patients?

Submission date
29/12/2018

Recruitment status
No longer recruiting

Registration date
19/02/2019

Overall study status
Completed

Last Edited
21/09/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
36% of patients without a history of insomnia developed sleep problem in the hospital. In this study, we aimed to answer the question of whether reducing noise, light, providing quiet times, earplugs and eye masks for hospitalized patients could reduce the insomnia rate and severity at discharge.

Who can participate?
Adult patients who are admitted to the medical floors. We require that our patients must be English speakers who are able to read, to hear and to understand our questions in the survey to screen for insomnia.

What does the study involve?
All the patients consented to the study will be given earplugs and eye masks at the time of their admission. They are given instructions to use them and are advised to use ear plugs/eye masks during the day or at night if needed. Patients were also informed of routine labs and vital sign check time range in the hospital. During that month, patients will be provided quiet time from 4pm to 5pm and at night from 10:00 PM to 5AM. During quiet time, lights were dimmed down in the patients' rooms and in the hallways. Televisions in patients' rooms that are not in use were turned off. Nurses, physicians, physical therapists, medical assistants were encouraged not to speak loudly or interrupt patients sleep unless for emergency cases.

What are the possible benefits and risks of participating?
Benefits: there is no monetary compensation but patients will be provided with free earplugs and eye masks to take home. Risks: This study poses minimal risks to participants because it only includes giving out earplugs and eye masks, reducing light and noise. No treatment will be altered during the study period.

Where is the study run from?
Single center, Medstar Harbor hospital in Baltimore, Maryland, United States.

When is the study starting and how long is it expected to run for?
July 2018 to September 2018

Who is funding the study?
Self-paid by principal investigator.

Who is the main contact?
An Thi Nhat Ho, nhatan01@gmail.com

Contact information

Type(s)
Public

Contact name
Dr An Ho

Contact details
1307 Missouri Ave
St Louis
United States of America
63104

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2018-028

Study information

Scientific Title
A pilot non-randomized control trial of providing quiet time, ear plugs, eye masks, reducing noise and light in improving sleep for patients in general medical wards

Study objectives
Providing quiet time, earplugs, eye masks, reducing noise and light in general medical ward will decrease the rate of insomnia in hospitalized patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medstar Research Institute institutional review board, 01/07/2018, 2018-028

Study design
Interventional non-randomised single-centre pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Insomnia

Interventions
All the patients consented to the study were given ear plugs and eye masks at the time of their admission. They are given verbal instructions to use them and were advised to use ear plugs/eye masks during the day or at night if needed. Patients were also informed of routine labs and vital sign check time range in the hospital. During that month, all the general medical wards in our hospital performed quiet time from 4pm to 5pm and at night from 10:00 PM to 5AM. During quiet time, lights were dimmed down in the patients' rooms and in the hallways. Televisions in patients' rooms that are not in use were turned off. Nurses, physicians, physical therapists, medical assistants were encouraged not to speak loudly or interrupt patients sleep unless for emergency cases. However, nurse driven protocols in our hospital to check on patient safety at night were still performed for both pre-intervention and intervention groups.

The research protocol during the research time was introduced to hospital employees during meeting sessions and by printed posters. Research staff also checked every day to maximize compliance with the protocol.

Intervention Type
Other

Primary outcome measure
The frequency of insomnia will be determined using the percentage of patients with insomnia (ISI>7) at the time of discharge.

Secondary outcome measures
1. Insomnia severity will be determined using the ordinal score on the insomnia severity index at the time of discharge.
2. Patient satisfaction will be determined using the objective ordinal satisfaction score of the patients on the scale from 0 to 5 with 5 being the best hospital experience and duration of hospital stay.

Overall study start date
02/01/2018

Completion date
01/10/2018

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Admitted to general medical floor
3. Able to read and write in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
190

Total final enrolment
215

Key exclusion criteria
1. Diagnosis of altered mental status
2. Dementia
3. Severe hearing deficit

Date of first enrolment
15/07/2018

Date of final enrolment
15/09/2018

Locations

Countries of recruitment
United States of America

Study participating centre

Medstar Harbor Hospital
3001 South Hanover Street
Baltimore
United States of America
212225

Sponsor information

Organisation
Medstar Harbor Hospital

Sponsor details
3001 South Hanover Street
Baltimore
United States of America
21225

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05mdb5j94

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
15/02/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Presented at the American Thoracic Society International Conference	19/05/2019	21/09/2021	No	No