Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effects of bright light exposure on sleepiness and oral temperature among hospital night shift staffs

Protocol summary

Study aim

Determining the effect of bright light intervention on sleepiness and oral temperature of hospital night workers

Design

Participants were randomly assigned to intervention groups 1 and 2. The intervention group 1 received a brilliant light for the first time for 2 nights. At the same time, the intervention group 2 was exposed to normal light and after 6 days (washing period), the intervention in each group was changed to the intervention used in the other group. The exposure level is three times a night (For 1 hour each time) and each of the people in the intervention group exposed to 2500 LUX (in the presence of the room in break time). The sample size was 70 in each group. The study was a phase three clinical trial.

Settings and conduct

The intervention was cross-over and double blinded. That the researchers and the participants were not aware of the type of light received. The intervention was among shift workers at the Asia Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participants will be fully satisfied with the participation in the research; Participants will be shift workers of the Asia Hospital in Tehran; participants must have been engaged in shift working for at least one year. Non Inclusion criteria: drugs or opioid use

Intervention groups

Intervention group 1: The participants received 2500 LUX light. Then they exposed to normal light 300LUX after 6-day wash out period. Intervention group 2: the participants received 300LUX normal light. Then they exposed to2500 LUX light after 6-day wash out period.

Main outcome variables

The sleepiness rate; oral temperature rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180412039280N1**
Registration date: **2019-01-04, 1397/10/14**
Registration timing: **retrospective**

Last update: **2019-01-04, 1397/10/14**
Update count: **0**

Registration date

2019-01-04, 1397/10/14

Registrant information

Name

mohsen poursadeghiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0084

Email address

mo.poursadeghiyan@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2017-07-23, 1396/05/01

Trial completion date

2017-07-23, 1396/05/01

Scientific title

Evaluation of the effects of bright light exposure on sleepiness and oral temperature among hospital night shift staffs

Public title
The effects of bright light exposure on sleepiness and oral temperature
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study. Shift Workers at the Asia Hospital in Tehran working more than one year at night shifts .
Exclusion criteria:
substances or drugs user
Age
To **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **147**
Actual sample size reached: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using Random numbers table
Blinding (investigator's opinion)
Double blinded
Blinding description
The current study was double-blind. The researchers and participants were unaware of the type of light received.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Social Welfare and Rehabilitation Sciences
Street address
Kodakyar Ave., Daneshjo Blvd.,Evin
City
Tehran
Province
Tehran
Postal code
1985713834
Approval date
2017-05-31, 1396/03/10
Ethics committee reference number
IR.USWR.Rec.1396.77

Health conditions studied

1

Description of health condition studied
sleepiness
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drowsiness
Timepoint
before exposure and after exposure
Method of measurement
Stanford sleepiness scale questionnaire

2

Description
Oral temperature
Timepoint
before exposure and after exposure
Method of measurement
Medical mercury thermomete

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The participants received 2500 LUX light. Then they exposed to normal light 300LUX after 6-day wash out period.
Category
Treatment - Devices

2

Description
Intervention group 2: the participants received 300LUX normal light. Then they exposed to2500 LUX light after 6-day wash out period.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Asia Hospital
Full name of responsible person
Mohsen Poursadeghiyan
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Kodakyar Ave., Daneshjo Blvd.,Evin
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1985713871
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Ahmad Ali Akbari Kamrani
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Kodakyar Ave., Daneshjo Blvd.,Evin
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akbarikamrani@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
contact.organization_id
0
Name of organization / entity
Full name of responsible person
Mohsen Poursadeghiyan
Position
Associate Professor
Latest degree
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Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the ethics of the host organization
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable