

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 to 2500 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

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Email address

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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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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

Street address

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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

Ph.D.

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

Occupational Health

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Person responsible for updating data

Contact

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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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