

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Radiance-Dimmer Devices Simulating Natural Sunlight Rhythm on the Plasma Melatonin Levels and Anxiety and Depression Scores of the Submarine Personnel

Protocol summary

Study aim

The determin effect of natural circadian sunlight shifts on plasma melatonin and the depression and anxiety levels in submarine personnel's.

Design

The study population consisted of two groups: control group: 26 each. No criteria for having a physical or mental illness; Awareness of the company; No use of drugs effective on the level of melatonin; lack of psychiatric disorders; lack of alcohol and other substance abuse; aged 21 to 30 years; randomly divided into two experimental and Control groups.

Settings and conduct

The experimental group uses artificial light from a natural cycle, such as sunlight, between 6am and 6pm for 5 days a week. From 6am, they automatically turn on and vary in intensity from the sun, while the control group will continue to experience their constant artificial light during the same period. The location of the research was a sub-surface work environment.

Participants/Inclusion and exclusion criteria

Participants are Iran's submarine personnel. They are healthy in terms of mental and physical health, gender-matched and healthy people between the ages of 21 to 30 years.

Intervention groups

The experimental group received natural light cycles such as sunlight between 6:00 AM and 6:00 PM for 5 days a week. For this purpose, four automatic light-emitting diodes were installed in the workshops, containing 400 light-hearted light-emitting diodes, such as sunlight, with intensity of radiation. From 6:00 AM it automatically became clear that the approximate time of sunrise and sunset was increased and the intensity of the sun was increased, and then the intensity of radiation shrank at a rate of about 68 lux per hour, and as a result, the light at 6 o'clock It was gone from noon.

Main outcome variables

Plasma levels of melatonin, depression scores and anxiety scores decreased significantly in the experimental group compared to the control group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161112030846N2**

Registration date: **2018-06-03, 1397/03/13**

Registration timing: **retrospective**

Last update: **2018-06-03, 1397/03/13**

Update count: **0**

Registration date

2018-06-03, 1397/03/13

Registrant information

Name

Khodabakhsh Ahmadi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

This study was funded by a grant from Baqiyatallah
University of Medical Sciences.

Expected recruitment start date

2016-01-21, 1394/11/01
Expected recruitment end date
 2017-01-20, 1395/11/01
Actual recruitment start date
 2016-01-21, 1394/11/01
Actual recruitment end date
 2017-01-20, 1395/11/01
Trial completion date
 empty

Scientific title
 Effect of Radiance-Dimmer Devices Simulating Natural Sunlight Rhythm on the Plasma Melatonin Levels and Anxiety and Depression Scores of the Submarine Personnel

Public title
 Determining the effect of dim regulation by devices radiating according to natural circadian sunlight shifts

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Underground employees who use artificial light only during the period of their presence No specific disease or chronic physical and mental illness Male Have at least 21 and a maximum of 30 years
Exclusion criteria:
 Taking medications that could affect serum melatonin levels including Having depression or any other major psychiatric disorders on DSM IV Having significant acute or chronic systemic disorders including type I diabetes mellitus, uncontrolled thyroid disorders, kidney/prostate/bladder problems which cause excessive urination, congestive heart failure, angina pectoris or other major cardiovascular disorders, hepatitis, asthma or severe respiratory allergies, stroke, Parkinson's disease, Alzheimer's disease, schizophrenia, epilepsy, oncologic disorders if less than 1 year since end of treatment, or chronic infections Use of hypnotics, melatonin, stimulants, or other medications that may affect melatonin levels (e.g. β blockers, drugs that affect prostaglandin synthesis, or drugs that activate hepatic melatonin metabolism) and unwillingness or inability to discontinue the occasional use of these medications for at least 4 weeks before beginning of the study

Age
 From **21 years** old to **30 years** old

Gender
 Male

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: **52**
 Actual sample size reached: **52**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The members of the two bunch of staff were randomly divided into two experimental and control groups.

Participants in the two groups did not differ significantly in terms of demographic characteristics such as gender, age, and educational level. In each group, 26 patients were tested and controlled.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

SheikhBahaie St. Mollasadra Ave.

City

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1435916471

Approval date

2017-02-15, 1395/11/27

Ethics committee reference number

IR.BMSU.REC.1395.232

Health conditions studied

1

Description of health condition studied

Anxiety and Depressive

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Anxiety

Timepoint

3 TIMES: Initiation, Middle and End of the study period

Method of measurement

Cattell's Anxiety Scale Questionnaire (IPAT)

2

Description

Depression

Timepoint

3 TIMES: Initiation, Middle and End of the study period

Method of measurement

Minnesota Multiple Personality Inventory (MMPI)

3

Description

plasma melatonin hormone

Timepoint

3 TIMES: Initiation, Middle and End of the study period

Method of measurement

Blood examination

Secondary outcomes

empty

Intervention groups

1

Description

experimental group, In order to lighting the environment, 4 automatic optic devices were installed at the halls where personnel from the case group were working in, containing lamps expelling sunlight and moonlit with radiant intensity were 400 lux. These optic devices were automatic and turned on since 6 am automatically , which were approximate time of sunrise, and in a modal that conformities with increment of natural radiance of sunlight, 68 lux added to their radiant intensity every hour, so that radiant intensity of these optic regulators reach to its radiant proxy at 12:00 o'clock which means 400 lux for each regulator device, and subsequently reducing their radiant intensity at a rate about 68 lux an hour, and at a result, the light would have been turned off at 6 o'clock PM, almost conformed with approximate time of the sunset.

Category

Prevention

2

Description

Control group: the control group continued their experience with constant artificial light during the same time period. After this time, the study variables were reanalyzed and compared to the baseline values.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Marine Forces

Full name of responsible person

Majid Hazrati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Hassan Saadat

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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

Bagheiat-allah University of Medical 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

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Khodabakhsh Ahmadi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Article is published Will be published in paper.

When the data will become available and for how long

2018

To whom data/document is available

Researchers and academics

Under which criteria data/document could be used

It is possible to mention the source of the research article

From where data/document is obtainable

An article that will be published will be available.

What processes are involved for a request to access data/document

An article that will be published will be available.

Comments