Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the circadian rhythm disturbance impacts on the human reward system, impulsivity and cognitive performance

Protocol summary

Study aim

The general aim of this study was to determine the effect of circadian rhythm disturbance on human reward system, impulsivity and cognitive function and the specific objectives are as follows Determination of circadian rhythm disorders in the subjects Determining the incidence of impulsivity in the subjects Determining the reward system in the subjects Determining cognitive function in the subjects Determining the reward circuit in the subjects Determining readiness for substance use and addictive behaviors

Design

Double-blind randomized controlled trial, the sample size in this study was selected with 80% power, significance level 0.05 and impact size 0.9 (17 people in each group) in the total sample size of 34,participants as Random blocks will be divided into intervention and control groups.

Settings and conduct

This study will be performed on the research site of Shahroud University of Medical Sciences for eleven days and during the experimental period, variables such as ambient light intensity, eating time and sleeping time will change in the experimental group but will not change in the control group.In this study, participants and analysts will not be aware of the study results of groups

Participants/Inclusion and exclusion criteria

inclusion: Male right handed Age category between 18 and 25 years Regular rhythm of sleep and wakefulness in the past month Exclusion: Having a general medical disorder that endangers a person's health during the experiment

Intervention groups

The duration of this study is eleven days and variables such as ambient light intensity, eating and sleeping time as previously described will change for the participants of the experimental group and for the participants of the group. Control will remain unchanged.

Main outcome variables

Cognitive functions, reward system, mood rhytmicity, substance use readiness, impulsivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210202050223N1**
Registration date: **2021-04-24, 1400/02/04**
Registration timing: **prospective**

Last update: **2021-04-24, 1400/02/04**
Update count: **0**

Registration date

2021-04-24, 1400/02/04

Registrant information

Name

Mohammad Niroumand Sarvandani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-13, 1400/02/23

Expected recruitment end date

2021-05-25, 1400/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the circadian rhythm disturbance impacts on the human reward system, impulsivity and cognitive performance

Public title
the effect of circadian rhythm disturbance on reward circuit and psychological functions

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Male gender right handed Age range between 18 and 25 years Regular rhythm of sleep and wakefulness in the past month (8 to 10) hours of sleep a night

Exclusion criteria:
Having a history of psychiatric disorder Having a history of substance abuse Use of psychiatric drugs Having a general medical disorder that endangers participants health during the test Having a history of brain trauma Having a metal body in the body, including platinum, fragments or iron particles Having an irregular rhythm of sleeping and waking in the last month (8 to 10) hours of sleep at night (night shift work) Having body mass index higher than 30

Age
From **18 years** old to **25 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
To equal the sample size in the two groups, the block method with a volume of 4 is used. For this purpose, 6 to four blocks will be created as follows 1- AABB 2- ABAB 3- ABBA 4- BBAA 5- BABA 6- BAAB Where A is for the intervention group and B is for the control group The random assignment will be done in such a way that a random number will be created in Excel from 0 to 9 first. Depending on which block the random number belongs to, the sequence of that block is used to assign the subjects to the control and intervention group.For example, if the random number generated is 6, the first person will be assigned to group B, the second person to group A, the third person to group A, and the fourth person to group B. To reach the calculated sample size, the random number creation will be repeated 9 times Because each time the task is assigned, four diseases are identified. It should be noted that if the random number generated is 7, 8, 9 and 0, it will be ignored. Envelopes in which the specified group is placed are used to conceal the allocation. Envelopes are numbered. After filling in the basic information of the people, an envelope is opened according to the word order of the people and the person is assigned to the desired group. To do this, 34 envelopes will be ready and individuals will be assigned to two groups. The methodology consultant determines the allocation sequence. The registration of participants and their entry according to the entry and exit criteria and obtaining informed consent is the responsibility of a trained psychologist. Then, if they are eligible, it assigns them to groups based on closed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
n this study, participants and analysts will not be aware of the results of the study. Also, in all outcome assessments conducted by questionnaires or interviews by a psychologist colleague, the research colleagues are unaware of how the participants are placed in the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahroud university of medical science

Street address
Shahroud University of Medical Sciences and Health Services, Hafte Tir Square, Shahroud, Iran

City
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Province
Semnan

Postal code
۳۶۱۴۷-۷۳۹۴۷

Approval date
2021-02-07, 1399/11/19

Ethics committee reference number
IR.SHMU.REC.1399.170

Health conditions studied

1

Description of health condition studied
circadian rhythm disorder (shift work type)

ICD-10 code
G47.26

ICD-10 code description
Circadian rhythm sleep disorder, shift work type

Primary outcomes

1

Description
Impulsivity score in Bart's Impulsivity Questionnaire
Timepoint
Beginning of the intervention (before the start of the intervention) and end of the intervention (immediately after the end of the intervention)
Method of measurement
Bart's Impulsivity Questionnaire

2

Description
assessment of Cognitive functions
Timepoint
Beginning of the intervention (before the start of the intervention) and end of the intervention (immediately after the end of the intervention)
Method of measurement
Brief Cognitive Rating Scale

3

Description
assessment of presence or absence of mood rhythmicity
Timepoint
Four hours before the intervention and four hours after the intervention
Method of measurement
Mood Rhythm Instrument (MRhI)

4

Description
Evaluation of the performance of the reward system (mesocortico limbic circuit)
Timepoint
Three hours before the intervention and three hours after the intervention
Method of measurement
Functional magnetic resonance imaging

5

Description
performance in high-risk decision test (due to reaction time)
Timepoint
Three hours before the intervention and three hours after the intervention
Method of measurement
Functional magnetic resonance imaging (GO/NO GO task)

6

Description
Vulnerability score for substance use and addictive behaviors test
Timepoint
Two hours before the intervention and two hours after the intervention
Method of measurement
Vulnerability to substance use and addictive behaviors test

Secondary outcomes

1

Description
Impulsivity score in Bart's Impulsivity Questionnaire
Timepoint
Beginning of the intervention (before the start of the intervention) and end of the intervention (immediately after the end of the intervention)
Method of measurement
Bart's Impulsivity Questionnaire

2

Description
assessment of Cognitive functions
Timepoint
Beginning of the intervention (before the start of the intervention) and end of the intervention (immediately after the end of the intervention)
Method of measurement
Brief Cognitive Rating Scale

3

Description
assessment of presence or absence of mood rhythmicity
Timepoint
Four hours before the intervention and four hours after the intervention
Method of measurement
Mood Rhythm Instrument (MRhI)

4

Description
Evaluation of the performance of the reward system (mesocorticolimbic circuit)
Timepoint
Three hours before the intervention and three hours after the intervention
Method of measurement
Functional magnetic resonance imaging

5

Description
performance in high-risk decision test (due to reaction time)
Timepoint
Three hours before the intervention and three hours after the intervention
Method of measurement
Functional magnetic resonance imaging (GO/NO GO task)

6

Description
Vulnerability score for substance use and addictive behaviors test

Timepoint
Two hours before the intervention and two hours after the intervention

Method of measurement
Vulnerability to substance use and addictive behaviors test

Intervention groups

1

Description
Intervention group: The intervention for participants lasts for 9 days, the first 3 days are related to getting used to the conditions of the study environment.from the fourth day, the circadian rhythm disturbance protocol will be applied In the first three days of the study, participants eat breakfast at seven in the morning, lunch at noon and dinner at seven in the evening. From the fourth day, the intervention is as follows: breakfast at seven in the morning, lunch at seven in the afternoon and dinner at twelve at night.Sleep patterns in this group are also planned in such a way that the participants of the intervention group are awake during the night with 450 lux light in the room and are allowed to sleep at eleven o'clock in the morning every day until seven o'clock in the evening with 90 lux light. And research assistants oversee the accurate implementation of this model.

Category
Lifestyle

2

Description
Control group: Participants in the control group are also present on the experimental site for 9 days,The meal times in the control group in all 9 days of presence in the experimental site are as follows: they eat breakfast at seven in the morning, lunch at noon and dinner at seven in the evening, and the patterns of sleeping and waking up are as follows: During the night, between eleven o'clock at night and seven o'clock in the morning, with 0 lux light, they can have a complete and normal night's sleep.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
دانشگاه علوم پزشکی شاهرود

Full name of responsible person
Mohammad Niroumand Sarvandani

Street address
Shahroud University of Medical Sciences and Health Services, Hafte Tir Square, Shahroud, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Mohammad Hassan Emamian

Street address
Shahroud University of Medical Sciences and Health Services, Hafte Tir Square, Shahroud, Iran.

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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
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Mohammad Niroumand Sarvandani

Position
Phd candidate

Latest degree
Master

Other areas of specialty/work
Neuroscience

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No.108,Saman dormitory,Semnan,Shahroud,Iran

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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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Position
Phd candidate

Latest degree
Master

Other areas of specialty/work
Neuroscience

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Person responsible for updating data

Contact

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Shahroud University of Medical Sciences

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Latest degree
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Other areas of specialty/work
Neuroscience

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All personal data of the participants will share without name and personal information (unidentified)

When the data will become available and for how long
the access period start 6 months after results publication

To whom data/document is available
researcher who are working in academic and scientific institutions

Under which criteria data/document could be used
the use of all data or documents for researcher for using in their research with reference to the source is allowed

From where data/document is obtainable
To researcher of this study,Mohammad Niroumand Sarvandani refer to email address: m.niroumand@shmu.ac.ir

What processes are involved for a request to access data/document
by sending an email to m.niroumand@shmu.ac.ir. all the demanded files will be provided to the applicant within 10 working days

Comments