Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of effect of sleep hygiene education and sleep reform education on emotional indicators and memory function in Shiraz traumatic brain injury patients.

Protocol summary

Summary

(1) Objectives: Study of effect of sleep hygiene education and sleep reform education on depression, anxiety and stress in Shiraz traumatic brain injury patients in 1393 and study of effect of sleep hygiene education and sleep reform education on memory function in Shiraz traumatic brain injury patients in 1393. (2) Design: Randomizing; 2-3 Trial phase; not blinded; without placebo. (3) Setting and conduct: After selecting their patients they were divided into intervention and control groups randomly.The intervention group were instructed and fill out the questionnaires. The control group filling out questionnaires but They not be manipulated. All patients completed the questionnaires after one and three months.Intervention group to be followed by telephon weekly. (4)sample volume: 60 (5) Participants including major eligibility criteria: Inclusions: The range of age 18-65 years old; ability of reading and writing 6 class at least; no previous disabler injury or due stroke injury. Exclusion: non inclination of patient for partnership in study; appearance severe psychiatric disorder; non appearance of sleep disorder. (6) Intervention: Sleep hygiene and reform education is given to the intervention group patients in a verbal one-hour sessions. In addition, two verbal follow up sessions with one and three-month interval and weekly telephone follow-up will be done. (7) main outcome : Improvement of sleep disorders in brain damage patients and improvement of emotional disorders and memory problems in brain damage patients. (8)Intervention time 2014.7.23 to 2014.12.21

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041917334N1**

Registration date: **2014-08-04, 1393/05/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-04, 1393/05/13

Registrant information

Name

Asieh Chanor

Name of organization / entity

Shiraz Medical sciense university

Country

Iran (Islamic Republic of)

Phone

+98 711230541019

Email address

chanor@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz medical sceinse university

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of effect of sleep hygiene education and sleep reform education on emotional indicators and memory

function in Shiraz traumatic brain injury patients.

Public title
Effect of sleep hygiene education on emotions and memory of Shiraz traumatic brain injury patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusions: The range of age 18-65 years old; Ability of reading and writing 6 class at least; No previous disabler injury or due stroke injury. Exclusion: Non inclination of patient for partnership in study; Appearance severe psychiatric disorder; Non appearance of sleep disorder.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Ethical committee of Shiraz medical sciences university
Street address
Zand street, Shiraz
City
Shiraz
Postal code
Approval date
2014-02-16, 1392/11/27
Ethics committee reference number
CT-92-6879

Health conditions studied

1

Description of health condition studied
trumatic brain injory
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Sleep disorders
ICD-10 code
G47.0
ICD-10 code description
Disorders of initiating and maintaining sleep(Inso(mnia)

Primary outcomes

1

Description
Sleep disorders
Timepoint
Before intervention, one month after intervention and 3 month after intervention
Method of measurement
Pittsburg sleep quality questionnaire(PSQI)

Secondary outcomes

1

Description
Memory function
Timepoint
Before intervention, one month and 3 month after intervention
Method of measurement
memory questionnaire (MFQ)

2

Description
emotional indicators (depression, anxiety and strees)
Timepoint
before intervention, one month and 3 month after intervention
Method of measurement
DASS questionnaire

Intervention groups

1

Description
Education of sleep hygiene done on intervention group.
Category
Behavior

2

Description
Any intervention done on control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid rajai hospital
Full name of responsible person
Hoseinali khalili
Street address
Chamran street, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Shiraz University of Medical Sciences
Full name of responsible person
Post frosh
Street address
Medical science university building, Zand street, Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz medical science university
Full name of responsible person
Asieh chanor
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Person responsible for scientific inquiries

Contact
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Arash Mani
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty