

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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 telephone 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 science 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 disabling 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 injury

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

Position

Student

Other areas of specialty/work

Street address

Zand street, shiraz

City

Shiraz

Postal code

Phone

+98 71 1826 2956

Fax

Email

Chanoratie@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz medical science university

Full name of responsible person

Arash Mani

Position

PhD in Cognitive Neuroscience

Other areas of specialty/work

Street address

Hafez hospital, chamran street, shiraz

City

Shiraz

Postal code

Phone

+98 71 1627 9319

Fax

Email

Mania@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz medical science university

Full name of responsible person

Asieh chanor

Position

Student

Other areas of specialty/work

Street address

Isargaran set, Rahmat street, Shiraz

City

Shiraz

Postal code

Phone

+98 71 1826 2956

Fax

Email

Chanoratie@yahoo.com

Web page address

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