

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of factors related to depression and mental health and determining the effect of sleep and wake training workshop on these factors and immunological factors in students of Shiraz University of Medical Sciences in 96

Protocol summary

Study aim

1) Determining the demographic characteristics of volunteer students of Shiraz University of Medical Sciences in the study group 2) Determining and comparing the mean scores of psychological profile (using Beck Anxiety and Depression Questionnaire, Petersburg Sleep Quality Questionnaire) Volunteer students of Shiraz University of Medical Sciences before and after the workshop At the end of the sixth month in the study group 3) Determining and comparing the immunological profile with the following tests in volunteer students of Shiraz University of Medical Sciences before and after the workshop and at the end of the sixth month in the study group Human IL-1 β Human IL-8 Human IFN- γ

Design

A controlled clinical trial with parallel, double-blind, randomized groups on 48 students was used for computerized randomization.

Settings and conduct

In this study, samples were collected and workshops were held in the medical school.

Participants/Inclusion and exclusion criteria

Student satisfaction, study at Shiraz University of Medical Sciences, absence of specific diseases including infectious diseases, diabetes, heart disease, psychological problems and such cases (with the diagnosis of the relevant doctor)

Intervention groups

Depression and anxiety questionnaires were filled out for the subjects before and after the intervention, and these individuals participated in two workshops. For the control group, the questionnaires were filled only at the same time and no training workshop was held.

Main outcome variables

Changing the level of safety factors after training

workshops

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140622018187N10**

Registration date: **2020-08-08, 1399/05/18**

Registration timing: **retrospective**

Last update: **2020-08-08, 1399/05/18**

Update count: **0**

Registration date

2020-08-08, 1399/05/18

Registrant information

Name

Sedighe Forouhari

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 987136474257

Email address

foruharis@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-05-21, 1397/02/31

Actual recruitment start date

2017-09-23, 1396/07/01
Actual recruitment end date

2018-05-21, 1397/02/31
Trial completion date
2018-08-22, 1397/05/31

Scientific title

Evaluation of factors related to depression and mental health and determining the effect of sleep and wake training workshop on these factors and immunological factors in students of Shiraz University of Medical Sciences in 96

Public title

Evaluation of factors related to depression and mental health and determining the effect of sleep and wake training workshop on these factors and immunological factors in students of Shiraz University of Medical Sciences in 96

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Student satisfaction, study at Shiraz University of Medical Sciences, absence of specific diseases including infectious diseases, diabetes, heart disease, psychological problems and such cases (with the diagnosis of the relevant doctor)

Exclusion criteria:

Dissatisfaction with research cooperation at any time during the research process, occurrence of any unexpected physical and psychological events

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **48**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Students will be divided into two equal groups based on simple random assignment based on simple research assignment, so that there will be about 24 people in each workshop group to provide better group and workshop training. It should be noted that randomization will be done based on a table of random numbers using a computer.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study and the patient and the researcher are unaware of how the groups are

assigned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Fatemeh School of Nursing and Midwifery, Namazi Hospital, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2018-08-07, 1397/05/16

Ethics committee reference number

96-01-106-14782

Health conditions studied

1

Description of health condition studied

depression and anxiety

ICD-10 code

f32

ICD-10 code description

F30-39

Primary outcomes

1

Description

Depression

Timepoint

Before and after the workshop and 3 and 6 months after the workshop

Method of measurement

Beck Anxiety and Depression Inventories

2

Description

Anxiety

Timepoint

Before and after the workshop and 3 and 6 months after

the workshop
Method of measurement
Beck Anxiety and Depression Inventories

3

Description
Blood safety factors
Timepoint
Before and 6 months after the workshop
Method of measurement
Immunological tests

4

Description
Sleep Quality
Timepoint
Before and after the workshop and 3 and 6 months after the workshop
Method of measurement
Petersburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Medical School
Full name of responsible person
Sedighe Forouhari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Unes Ghasemi
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Technology and Research Office, Research Deputy ,
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president@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Sedighe Forouhari
Position
Ph.D , Supervisor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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