

# 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 $\beta$  Human IL-8 Human IFN- $\gamma$

##### 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  
**Street address**  
Shiraz  
**City**  
Fars  
**Province**  
Fars  
**Postal code**  
7153113311  
**Phone**  
+98 71 3726 6811  
**Email**  
foruharis@sums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr Unes Ghasemi  
**Street address**  
Technology and Research Office, Research Deputy ,  
Shiraz University of Medical Science, Zand Street,  
Shiraz  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
۷۱۳۳۶ - ۷۱۳۴۸  
**Phone**  
+98 71 3230 5410  
**Email**  
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  
**Street address**  
College Of Nursing Midwifery, Shiraz  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
71345-1978  
**Phone**  
+98 71 1647 4257

**Email**

forouharism@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Sedighe Foruhari

**Position**

Ph.D , Supervisor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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**Phone**

+98 71 1647 4257

**Email**

forouharism@yahoo.com

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Sedighe Foruhari

**Position**

Ph.D , Supervisor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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Fars

**Postal code**

71345-1978

**Phone**

+98 71 1647 4257

**Email**

forouharism@yahoo.com

**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