

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The impact of correct training sleep and wakefulness on anxiety, depression and some related hormones in infertile women referring to Hazrat Zeynab( P.B.U.H.) Hospital 2018-2019

#### Protocol summary

##### Study aim

The impact of correct training sleep and wakefulness on anxiety, depression and some related hormones in infertile women referring to Hazrat Zeynab( P.B.U.H.) Hospital

##### Design

A randomized controlled clinical trial with parallel groups

##### Settings and conduct

The researcher, after receiving a code of ethics from the University Ethics Committee and receiving the IRCT code and obtaining a sampling permit from the university, goes to the research setting and, after obtaining permission from the hospital authorities, first describes the aims of the study for patients who meet the inclusion criteria. And after obtaining written informed consent, the questionnaires for infertile women will be completed first and then those that meet the criteria mentioned in the study (low sleep quality (greater than or equal to 5) based on the Pittsburgh Depression Inventory). Mild (score less than 18) based on Beck Depression Inventory and mild anxiety (low score) Based on Beck's Anxiety Questionnaire (15), the blood samples were taken on the third day of the menstrual cycle to measure blood levels of 10 cc (TSH, FSH, LH, PROLACTIN).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: poor sleep quality, mild depression and mild anxiety, referred to infertility center of Hazrat Zeinab Hospital for infertility treatment, informed consent to participate in non-mental health research, absence of internal diseases , No drugs, alcohol, sleep medications, no stressful or disturbing event occurring in the last 6 months, no unusual occurrence in the last 3 months, no use of hormonal drugs at least 4 to 6 weeks before blood sampling, no abnormal bleeding or amenorrhea . Exclusion criteria: Patients' dissatisfaction with continuing research, pregnancy at each stage of research

##### Intervention groups

Intervention group: Sleep and wake pattern workshop

##### Main outcome variables

Hormone levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140622018187N8**

Registration date: **2020-03-04, 1398/12/14**

Registration timing: **retrospective**

Last update: **2020-03-04, 1398/12/14**

Update count: **0**

##### Registration date

2020-03-04, 1398/12/14

##### 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

2018-05-22, 1397/03/01

##### Expected recruitment end date

2019-04-20, 1398/01/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The impact of correct training sleep and wakefulness on anxiety, depression and some related hormones in infertile women referring to Hazrat Zeynab( P.B.U.H.) Hospital 2018-2019

**Public title**

The effect of sleep and wake training on anxiety, depression and some related hormones in infertile women

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Poor sleep quality (greater than or equal to 5) based on the Pittsburgh questionnaire, mild depression (score less than 18) based on the Beck Depression Inventory and mild anxiety (score less than 15) based on the Beck Anxiety Inventory. Have been referred to the Infertility Center of Hazrat Zeinab Hospital for infertility treatment. Have informed consent to participate in the research and complete the relevant form Absence of mental and mental illnesses to the diagnosis of the relevant physician Absence of internal diseases to the doctor's diagnosis Absence of internal diseases to the doctor's diagnosis No stressful or disturbing event has occurred in the last 6 months Unusual situations such as traveling, changing jobs and having stressful jobs, shifting diets, and the like over the last 3 months that have caused a change in sleep patterns Not taking hormone drugs at least 4-6 weeks before blood sampling Abnormal bleeding or amenorrhea in a way that there is no possibility of bleeding on the third day of the menstrual cycle.

**Exclusion criteria:**

Patient dissatisfaction with continuing to participate in research at each stage Incidence of each of the 4 to 10 items listed in the inclusion criteria in each research step Pregnancy at each stage of research

**Age**

From **15 years** old to **44 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **130**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The permutation block randomization method with four blocks will be used. We assign different positions to the numbers 1 to 6, respectively. Now, using the random

number table, we extract the numbers from the table and, depending on one of the numbers from 1 to 6, select any of the blocks assigned to these numbers until 36 blocks of 4 are selected. If the numbers zero, 7, 8, and 9 are omitted, we will continue to provide a complete list of the total sample size in both case and control groups.

**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**

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**

۷۱۹۳۶ - ۷۱۹۳۶

**Approval date**

2019-01-23, 1397/11/03

**Ethics committee reference number**

IR.SUMS.REC.1398.010

**Health conditions studied****1****Description of health condition studied**

physical and mental health

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Blood hormones (TSH, FSH, LH, PROLACTIN) will be measured on day 3 of the menstrual cycle.

**Timepoint**

Blood sampling at baseline and then 6 months after the last intervention

**Method of measurement**

Blood sampling and hormonal testing

## Secondary outcomes

### 1

#### Description

mental health

#### Timepoint

At the beginning of the study and 1 month and 6 months after the end of the intervention

#### Method of measurement

- Pittsburgh PSQI questionnaire- Beck Depression Inventory (BDI)- BAI Anxiety Inventory- Demographic questionnaire (including information on age, education, occupation and couple, history of infertility by type and cause, socioeconomic status, body mass index, distance from previous pregnancy (if secondary), medication use, smoking, alcohol and Tobacco and Paraclinical Tests and Records)Depression Inventory and Mild Anxiety (score less than 15) based on Beck Anxiety Inventory

## Intervention groups

### 1

#### Description

"Intervention group: 1. Conducting a workshop, 2. Weekly follow up and completing the questionnaires 1 and 6 months after the end of the intervention, 3. 6 months after intervention"

#### Category

Behavior

### 2

#### Description

Control group:1. Continuing with their usual process (no intervention, no Workshop for the control group) 2. Weekly follow up and questionnaires 1 and 6 months after the end of intervention, 3. Blood tests 6 months after intervention "

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hazrat Zeinab Hospital

##### Full name of responsible person

Leila Zebardast

##### Street address

Falake khatoon , Shiraz , Iran

##### City

Shiraz

##### Province

Fars

##### Postal code

۷۱۵۳۸۱۳۳۱۱

#### 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

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##### Postal code

۱۴۳۳۶ - 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?

No

#### Title of funding source

Research Council of 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

Reproductive Health

##### Street address

College Of Nursing Midwifery, Shiraz

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forouharism@yahoo.com

## Person responsible for scientific inquiries

### Contact

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Shiraz University of Medical Sciences  
**Full name of responsible person**  
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Ph.D , Supervisor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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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