Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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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
۱۳۱۱۹ - 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
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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 , Shiraz University of Medical Science, Zand Street, Shiraz
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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
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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