Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of lifestyle-based combined intervention program on sleep quality and occupational fatigue of female nurses

Protocol summary

Study aim
Determining the impact of a combined intervention program based on lifestyle on the quality of sleep and occupational fatigue of female nurses

Design
The clinical trial has two intervention and control groups with parallel, randomized groups

Settings and conduct
Female nurses working in Taleghani Hospital and Imam Khomeini Hospital in Urmia who have the inclusion criteria to the study, will be selected and divided into intervention and control groups, and sleep hygiene, progressive muscle relaxation techniques and Aerobic sports will be taught to them. No intervention will be done for the control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range from 22 to 45, Not having any physical or mental illness or any condition that causes fatigue such as anemia, kidney failure and multiple sclerosis during the last 6 months, Having a bachelor's degree in nursing, Not taking special drugs that affect fatigue, Having rotating work shift, No pregnancy, No breastfeeding, Not having thyroid diseases during the study

Intervention groups
Intervention group: 1) Teaching the principles of sleep hygiene during a virtual session with Sky Room.The file of this content will also be placed on the WhatsApp channel and Doing it daily for up to two months. 2)Teaching Jacobson's method of progressive muscle relaxation by sending an audio file and educational content to the WhatsApp channel and tracking its daily performance for two months. 3) Sending the aerobic exercises prepared by the federation coach to the WhatsApp channel, which will be done by the intervention group on 5 days of the week for two months. Control group: no intervention will be done.

Main outcome variables
quality of sleep, occupational fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161227031588N5**
Registration date: **2022-11-06, 1401/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-06, 1401/08/15**
Update count: **0**

Registration date
2022-11-06, 1401/08/15

Registrant information

Name
Haleh Ghavami
Name of organization / entity
Urmia University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 44 3275 4962
Email address
ghavami.h@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-01, 1401/08/10

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of lifestyle-based combined intervention program on sleep quality and occupational fatigue of female nurses

Public title
effect of lifestyle-based combined intervention on sleep quality and occupational fatigue of nurses

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
age range from 22 to 45 not having any physical or mental illness or any condition that causes fatigue such as anemia, kidney failure and multiple sclerosis in the past 6 months having a bachelor's degree in nursing not taking special drugs that affect fatigue rotating shift no pregnancy no breastfeeding not having thyroid diseases during the study

Exclusion criteria:

Age
From **22 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to determine the samples, a random method will be used. For randomization, the names of the people will be put into a pot, then the first one will be randomly placed in the intervention group and the second one will be placed in the control group, and this will continue until there are 60 people. In this way, the names of the nurses in Taleghani Hospital and similar departments in Imam Khomeini Hospital will be listed, and 30 people will be considered for the intervention group and 30 people will be considered for the control group.

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 Urmia University of Medical Sciences

Street address
Orjhans Street, Resalat Blvd, Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5714985454

Approval date
2022-05-25, 1401/03/04

Ethics committee reference number
IR.UMSU.REC.1401.092

Health conditions studied

1

Description of health condition studied
Sleep Quality

ICD-10 code
Y98

ICD-10 code description
Lifestyle-related condition

2

Description of health condition studied
Occupational Fatigue

ICD-10 code
Z73.5

ICD-10 code description
Social role conflict, not elsewhere classified

Primary outcomes

1

Description
sleep quality

Timepoint
Before and after the intervention

Method of measurement
Pittsburgh Sleep Quality Questionnaire

2

Description
occupational fatigue

Timepoint
Before and after the intervention

Method of measurement
Swedish Occupational Fatigue Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1) teaching the principles of sleep hygiene (using a diet containing tryptophan, not consuming caffeine-containing foods before sleep, having enough physical activity and rest during the day and sleeping between 7 and 8 hours at night) to the intervention group. The training will include a virtual meeting with Skyroom and the file of this content will also be placed on the WhatsApp channel. The daily observance of these principles will be followed up through a self-reporting checklist completed by each person.2) Training of progressive muscle relaxation technique by Jacobson method, which training will be done by sending an audio file and educational content to the WhatsApp channel, and the daily performance of this technique will be followed for two months through a self-reporting checklist completed by each person.3) Sending aerobic exercises prepared by the coach of the sports federation. The prepared exercises will be sent to the WhatsApp channel of the intervention group, which will be carried out 5 days a week for two months by the members of the intervention group.

Category
Prevention

2

Description
Control group: no intervention will be done. At first, the questionnaires of Swedish occupational fatigue and sleep quality of Pittsburgh will be filled by the members of the control group, and after two months these questionnaires will be completed again by these people.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Taleghani Hospital, Urmia

Full name of responsible person
Farzane Zafarramazanian

Street address
Ayatollah Taleghani Hospital, Kashani Street, Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5714985454

Phone
+98 921 103 8223

Email
z.farzane.8223@gmail.com

2

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Urmia

Full name of responsible person
Farzane Zafarramazanian

Street address
Imam Khomeini Hospital, Ershad Boulevard, Modarres Boulevard, Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5714985454

Phone
+98 44 3234 8422

Email
z.farzane.8223@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Saber Gholizadeh

Street address
Orjhans Street, Resalat Blvd

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
+98 44 3193 7224

Email
saber_gholizadeh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Urmia 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

Oroumia University of Medical Sciences

Full name of responsible person
Haleh Ghavami

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Pardis Nazlou, 11 km of Nazlou Road, Urmia, Iran

City
Urmia

Province
West Azarbaijan

Postal code
5714985454

Phone
+98 44 3275 4961

Email
haleh_ghavami@yahoo.co.uk

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Haleh Ghavami

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
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Postal code
5714985454

Phone
+98 44 3275 4961

Email
haleh_ghavami@yahoo.co.uk

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Haleh Ghavami

Position
Assistant Professor

Latest degree
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Other areas of specialty/work
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Province
West Azarbaijan

Postal code
5714985454

Phone
+98 44 3275 4961

Email
haleh_ghavami@yahoo.co.uk

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Individual data of participants can be shared after de-identification.

When the data will become available and for how long
Three months after the results are published

To whom data/document is available
Researchers working in academic and scientific centers

Under which criteria data/document could be used
The use of documentation in research

From where data/document is obtainable
by Email: z.farzane.8223@gmail.com

What processes are involved for a request to access data/document
by Email: z.farzane.8223@gmail.com

Comments