Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparative of the Effects of Hatha Yoga exercise and Benson Relaxation on Sleep Quality in Postmenopausal Women with COVID-19: A randomized controlled trial Study

Protocol summary

Study aim
Comparative evaluation of the Effects of Hatha Yoga exercise and Benson Relaxation on Sleep Quality in Postmenopausal Women with COVID-19

Design
Clinical trial with control group, with parallel, randomized groups, 99 children

Settings and conduct
Approval of the research plan in the university ethics committee. At the beginning of the study, complete the demographic characteristics checklist and the Pittsburgh Sleep Quality Index. Intervention Group 1: Cold Spray: Interventions will be conducted according to the protocol, over 8 sessions, each lasting 1 hour, with 1 session per week, for a total of 8 weeks. Intervention Group 2: Acupressure: Interventions include 8 sessions, each lasting 1 hour, with 1 session per week, conducted over a total of 8 weeks according to the protocol. After completing the interventions, the Pittsburgh Sleep Quality Index will be completed again. The interventions will take place in a room at the women's clinic to ensure privacy and comfort for the participants.

Participants/Inclusion and exclusion criteria
Admission requirements: Age 45 years and older. Conditions of non-entry: Severe underlying diseases, such as heart diseases, type 1 diabetes, or psychiatric disorders.

Intervention groups
Intervention Group 1: Hatha Yoga Exercise: In this group, participants will first be placed in the Shavasana (corpse) pose for 10 minutes, during which mind control techniques will be taught. Then, they will perform light exercises for 30 minutes. Intervention Group 2: Benson Relaxation: In this group, the Benson relaxation method will be taught to participants in a single 60-minute group session held in person. Control group: non-intervention: this training group will not be given.

Main outcome variables
The Pittsburgh Sleep Quality Index

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200107046044N6**
Registration date: **2025-06-10, 1404/03/20**
Registration timing: **prospective**

Last update: **2025-06-10, 1404/03/20**
Update count: **0**

Registration date
2025-06-10, 1404/03/20

Registrant information
Name
Mohammadsajjad Mousavi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-07-23, 1404/05/01
Expected recruitment end date
2025-11-01, 1404/08/10
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative of the Effects of Hatha Yoga exercise and Benson Relaxation on Sleep Quality in Postmenopausal Women with COVID-19: A randomized controlled trial Study

Public title

A Comparative of the Effects of Hatha Yoga exercise and Benson Relaxation on Sleep Quality in Postmenopausal Women with COVID-19

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to communicate and respond to the questions of the Pittsburgh Sleep Quality Index Age 45 years or older Consent to participate in the study and signing the informed consent form Having had COVID-19 during the recovery or convalescence period Scoring 5 or higher on the Pittsburgh Sleep Quality Index Not using sleeping medications No prior training or participation in studies similar to the current research within the past 6 months

Exclusion criteria:

Lack of willingness to participate in the study Not meeting the study inclusion criteria Severe underlying diseases, such as heart diseases, type 1 diabetes, or psychiatric disorders Physical or mental disability; individuals who are unable to perform yoga or relaxation exercises due to their physical or mental condition

Age

From **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Block random assignment will be done in such a way that according to the number of study groups (three groups) consisting of intervention 1 (Hatha Yoga), intervention 2 (Benson Relaxation) and control and calculated based on the factorial law, i.e. 3!= 3×2×1= 6, all the possible arrangement modes of people will be compiled based on the table below, considering A for intervention group 1 (Hatha Yoga), B for intervention group 2 (Benson Relaxation) and C for control group: 1 2 3 4 5 6 ABC ACB BAC BCA CAB CBA Then, since the estimated sample size was 99 people, in each block, three samples, each representative of a study group and their arrangement order was also different, from these blocks, placement sampling will be done. After the study objectives are fully explained, eligible research samples will be selected and, based on the time priority of referral, each of them will be assigned a code. By matching that number with the block random allocation list, the patients participating in the study will be assigned to one of the intervention 1 (Hatha Yoga), intervention 2 (Benson Relaxation), and control groups. This process will continue until the estimated sample size is completed.

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 Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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Approval date

2025-04-23, 1404/02/03

Ethics committee reference number

IR.YUMS.REC.1404.011

Health conditions studied

1

Description of health condition studied

Coronavirus 2019 (Covid-19)

ICD-10 code

u07.1

ICD-10 code description

U07.1: COVID-19, Virus identified

Primary outcomes

1

Description

Sleep quality score from the Pittsburgh Sleep Quality Index

Timepoint

Before and after the interventions

Method of measurement
The Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Hatha Yoga Exercise: In this group, during the initial sessions, the researcher along with the instructor will first place the participants in the Shavasana (corpse) pose for 10 minutes and teach mind control techniques. Then, for 30 minutes, participants will perform light exercises including 4 movements in the lying position, 4 movements in the seated position, and 4 movements in the standing position. An important point is that after each movement, mindful attention to the limbs and breathing will be practiced. In all three positions, physical exercises will be combined with breathing exercises and relaxation techniques. Over subsequent sessions, the exercises will progress and increase from beginner to intermediate levels. The exercise program will be adjusted and conducted at least one to two hours after breakfast or a light lunch, at home, on a yoga mat or at minimum a quiet place with a soft carpet, in a moderate climate (neither cold nor hot). The interventions include 8 sessions, each lasting 1 hour, with 1 session per week, conducted over a total period of 8 weeks according to the protocol.

Category
Lifestyle

2

Description
Intervention Group 2: Benson Relaxation:In this group, initially, the Benson relaxation method will be taught to the participants in a single 60-minute group session held in person. Then, the interventions will be carried out according to the protocol. The interventions include 8 sessions, each lasting 1 hour, with 1 session per week, conducted over a total period of 8 weeks according to the protocol.

Category
Lifestyle

3

Description
Control group: non-intervention: There will be no intervention in this group.

Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajjad Hospital
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3

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
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Full name of responsible person
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Person responsible for updating data

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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