

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effectiveness of occupation-based interventions in improving sleep quality of patients recovered from COVID-19

Protocol summary

Study aim

Effectiveness of occupation-based occupational therapy interventions in managing sleep quality of COVID-19 recovered patients with sleep quality disorders in three areas: person, environment, and occupation

Design

This is a double-blind randomized clinical trial with the comparison group, in which 86 eligible patients will be randomly assigned through block randomization to the intervention and the control groups

Settings and conduct

This study will conduct with counseling sessions and the educational package of occupation-based and sleep health interventions in a double-blind manner(the participant and the researcher and the outcome assessor are blind) in Hamedan Red Crescent, Occupational Therapy Clinic in Nahavand city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least one month and at most three months have passed since COVID-19 was positive Based on the Mini-Mental State Examination score of 23 and above Have a sleep disorder based on the Petersburg questionnaire and get a score higher than 5 Exclusion criteria: Reluctance to attend study Occurrence of stresses such as recurrence of COVID-19

Intervention groups

1. Intervention group: Sleep management occupational therapy interventions in 15 sessions of 30 minutes over one month 2. Control group: Common sleep hygiene tips in one session

Main outcome variables

Quality of sleep

General information

Reason for update

Acronym

RCT

IRCT registration information

IRCT registration number: **IRCT20210821052244N1**

Registration date: **2023-03-06, 1401/12/15**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-06, 1401/12/15**

Update count: **0**

Registration date

2023-03-06, 1401/12/15

Registrant information

Name

saideh sadat mortazavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1572

Email address

s.mortazavi.ot@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-04-18, 1402/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of occupation-based interventions in improving sleep quality of patients recovered from COVID-19

Public title

Occupational therapy interventions in sleep quality

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having reading and writing skills At least one month and at most three months have passed since COVID-19 was positive Body mass index between 18.5 to 27 25 -50 years old An acceptable level of cognitive function, i.e. a score of equal or greater than 23 on the Mini-Mental State Examination Pittsburgh Sleep Quality Index \geq 5 Without known chronic diseases such as Progressive Neurological Disorders, Multiple Sclerosis, and Acute Cancer

Exclusion criteria:

Reluctance to attend study Alcohol or drug abuse Being menopausal Pregnant females

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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 University of Social Welfare and Rehabilitation Sciences

Street address

Velenjak, Daneshjoo Blvd, Koodakyar ave., University of Social Welfare and Rehabilitation Sciences

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Postal code

6591616563

Approval date

2022-05-18, 1401/02/28

Ethics committee reference number

IR.USWR.REC.1401.009

Health conditions studied

1

Description of health condition studied

Sleep disorder

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description

Sleep quality

Timepoint

Before the intervention, one week after the intervention, one month after the intervention

Method of measurement

Petersburg Sleep Quality Questionnaire

2

Description

Subjective quality of sleep

Timepoint

Before the intervention, one week after the intervention, one month after the intervention

Method of measurement

Petersburg Sleep Quality Questionnaire

Secondary outcomes

1

Description

Sleep duration

Timepoint

Before the intervention, one week after the intervention, one month after the intervention

Method of measurement

Petersburg Sleep Quality Questionnaire

2

Description

Sleep latency

Timepoint

Before the intervention, one week after the intervention, one month after the intervention

Method of measurement

Petersburg Sleep Quality Questionnaire

3

Description

Sleep onset and maintenance

Timepoint

Before the intervention, one week after the intervention, one month after the intervention

Method of measurement

Petersburg Sleep Quality Questionnaire

Intervention groups

1

Description

Intervention group: sleep management occupational therapy interventions in 15 sessions, including 5 sessions per week, will be thirty minutes in the form of 8 individual sessions and 7 training workshop sessions. The content of the sessions includes an introduction to sleep, providing good sleep exercises, teaching behavioral and individual strategies, teaching environmental strategies, and balance in occupation. Meetings are face-to-face, but there will be the possibility of virtual communication and phone calls to answer possible questions.

Category

Rehabilitation

2

Description

Control group: Common sleep hygiene recommendations in one session thirty-minute sessions including setting the clock and sleeping conditions

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Headquarters for the fight and prevention of Coronavirus disease (COVID-19) in Hamadan

Full name of responsible person

Saideh Sadat Mortazavi

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Hamadan University of Medical Science, St. Shahid Fahmideh, Hamadan. Iran.

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Recruitment center

Name of recruitment center

Brain and Neurology Clinics

Full name of responsible person

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Recruitment center

Name of recruitment center

Adult Psychiatric Clinics

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr Hamidreza Khankeh

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<https://researchdeputy.uswr.ac.ir/index.jsp?fkeyid=&siteid=56&pageid=15376>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Saideh Sadat Mortazavi

Position

Ph.D. student of occupational therapy

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor

Latest degree

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Person responsible for updating data

Contact

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Position

Professor

Latest degree

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Other areas of specialty/work

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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