Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of respiratory-physical exercises on fatigue and quality of life of nurses caring for COVID-19 patients in the Intensive Care Unit

Protocol summary

Study aim

Determining the effectiveness of respiratory-physical exercises on fatigue and quality of life of nurses caring for COVID-19 patients in the intensive care unit

Design

This is a clinical trial study in which samples are selected by convenience sampling method and then divided into two groups of experimental and control by block randomization method.

Settings and conduct

Study place: Amir Al-Momenin Hospital. Assignment of samples into two groups of intervention and control; then the severity of fatigue and quality of life are measured using the Nurses' Severity of Fatigue Scale and the World Health Organization Quality of Life Questionnaire. Then, the samples in the intervention group are given respiratory-physical movements and exercises in such a way that for 4 weeks and 3 times a week for 35 minutes of respiratory-physical movements and exercises, including: 10 minutes of respiratory exercises, 10 minutes of exercises. Physically and at the end of 15 minutes is Benson's relaxation technique.

Participants/Inclusion and exclusion criteria

At least 6 months of work experience in the intensive care unit; employed as a nursing team in intensive care units of coronary patients; no participation in yoga and meditation preparation courses; consent to participate in the study; no movement limiting diseases, musculoskeletal disorders, heart and respiratory diseases, neurological and psychiatric diseases. Exclusion criteria: cancellation of study at any stage; not doing exercises less than 2 times a week.

Intervention groups

Intervention: physical breathing exercises in which members of the intervention group perform physical breathing movements twice a week for 35 minutes for 4 weeks. The control group does not do any exercises.

Main outcome variables

Fatigue and Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210310050663N1**
Registration date: **2021-05-31, 1400/03/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-31, 1400/03/10**
Update count: **0**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

ahmad darvishi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3465 6270

Email address

a.darvishi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of respiratory-physical exercises on fatigue and quality of life of nurses caring for COVID-19 patients in the Intensive Care Unit

Public title
The effect of respiratory-physical exercises on fatigue and quality of life

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
At least 6 months of work experience in the intensive care unit, working as a nursing team (nursing, nursing assistant, nursing associate, nursing expert, master or doctoral nurse) in the intensive care unit where coronary patients are hospitalized Have not attended yoga and meditation preparation classes Satisfaction with participation in the study No known limiting motor diseases, musculoskeletal disorders, heart and respiratory diseases, neurological and psychiatric diseases

Exclusion criteria:
Withdrawal at any stage Complications of yoga movements Do not do exercises less than 2 times a week

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, research units are divided into two groups of intervention and test using block method by random allocation, so that in terms of age, sex, level of education and work experience in the intensive care unit of patients with Covid 19 are homogeneous. For this purpose, first, according to the variables that need to be homogenized, the class is considered for all possible situations of the research units, and after assigning the code to the nurses, it is placed in the block equivalent to their characteristics. Then, the first person of each block is randomly placed in one of the research groups, and each of the next people of each block, according to the characteristics they have about the variables considered for homogenization, is placed in a group with which people There are fewer features in that 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 Arak University of Medical Sciences

Street address
Basij Square of Arak University of Medical Sciences

City
Arak

Province
Markazi

Postal code
38481-70002

Approval date
1993-05-17, 1372/02/27

Ethics committee reference number
IR.ARAKMU.REC.1399.328

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID19,virus identified

Primary outcomes

1

Description
Fatigue score in the Rasooli Nurses Fatigue Questionnaire

Timepoint
At the beginning of the study then after the end of the intervention

Method of measurement
Rasooli Nurses Fatigue Questionnaire

2

Description
Nurses' quality of life score based on the World Health Organization quality of life questionnaire

Timepoint
At the beginning of the study then after the end of the intervention

Method of measurement
World Health Organization quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, respiratory-physical exercises are performed twice a week for 4 weeks and 35 minutes each time.
Category
Behavior

2

Description
Control group: No special intervention is performed on the control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al-Momenin Hospital
Full name of responsible person
Ahmad Darvishi
Street address
Amir Al-Momenin Hospital, Basij Square
City
Arak
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3848176941
Phone
+98 86 3417 3601
Email
it-amiralmomenin@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Basij Square of Arak University of Medical Sciences
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Email
alikamaliir@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Ahmad Darvishi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Ahmad Darvishi

Position
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Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Information about the findings of nurses' fatigue and quality of life questionnaires

When the data will become available and for how long
Access period starts 3 months after the results are published

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
Requests can be sent via existing email.

From where data/document is obtainable
To receive the documents, send a request to the e-mail of Mr. Ahmad Darvishi.

What processes are involved for a request to access data/document
The request will be answered immediately after sending the request and reviewing it.

Comments