

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing differences female and male on oxygenation, anxiety, performance and quality of life after physiotherapy in hospitalized patients with COVID-19

Protocol summary

Study aim

The purpose of this study is to investigate the effect of physical therapy exercises on the amount of oxygenation, level of anxiety, stress, performance and quality of life in hospitalized female and male patients affected by COVID-19 virus.

Design

Before- after clinical trial study include of 24 female and 24 male COVID-19 patients, without randomization and blinding.

Settings and conduct

Hospitalized patients in the Sina hospital who affected with COVID-19 with inclusion criteria will be enter to study. Physiotherapy exercises includes of chest and limb exercises are prescribed. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patients (20 and 65 years) who are affected by COVID-19 viruses. The hospitalization period is at least one to two weeks.
Exclusion criteria: Patients admitted on the intensive care unit or discharged from the intensive care unit. Also, patients with orthopedic, neurological and systemic disorders and pregnant women are not included in the study.

Intervention groups

Physiotherapy exercises includes of chest and limbs exercises are prescribed in female and male hospitalization patients. The setting of exercises will depends on patients conditions .

Main outcome variables

Quality of life; function; stress and anxiety; rate of oxygen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220719055493N1**

Registration date: **2022-09-13, 1401/06/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-13, 1401/06/22**

Update count: **0**

Registration date

2022-09-13, 1401/06/22

Registrant information

Name

Aliaa Resan Shnen Alabbas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 3939

Email address

aliaaamil828@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing differences female and male on oxygenation,

anxiety, performance and quality of life after
physiotherapy in hospitalized patients with COVID-19

IR.TUMS.FNM.REC.1401.040

Public title

Difference between male and female after physiotherapy
in COVID patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Female and male patients between 20-65 years old
Duration of hospitalization from one up to 2 weeks
Patients not admitted on ICU or discharged from ICU

Exclusion criteria:

Patients with orthopedic disorders, systemic disease
Neurological disorders Pregnant females

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of faculty of rehabilitation in Tehran
University of Medical Sciences

Street address

Pich-e- Shemiran, Enghelab Avenue, Faculty of
rehabilitation

City

Tehran

Province

Tehran

Postal code

1148965111

Approval date

2022-07-06, 1401/04/15

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Physiotherapy of patients affected with COVID

ICD-10 code

U07.1

ICD-10 code description

COVID- 19 virus infection

Primary outcomes

1

Description

Assessment of quality of life

Timepoint

Before hospitalization and after discharge

Method of measurement

Arabian version of Short-Form health survey
questionnaire (SF-36)

2

Description

Assessing performance

Timepoint

Before hospitalization and after discharge

Method of measurement

By measuring of distance in 6- min walking test

3

Description

Assessment of anxiety and stress.

Timepoint

Before hospitalization and after discharge

Method of measurement

Arabic version of Depression Anxiety Stress Scale-21By
questionnaire

4

Description

Measurement of oxygenation level

Timepoint

Before hospitalization and after discharge

Method of measurement

Oxiometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Breathing exercises related to the lungs (respiratory physiotherapy) + movements and exercises of upper and lower limbs prescribed according to order and patients' conditions during hospitalization. The duration of hospitalization and set of exercises was different among patients. Evaluations were done at the beginning of treatment and before discharge of hospital.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospitals

Full name of responsible person

Khadijeh Otadi

Street address

Sina Hospital, Hasan Abad square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Quds street, Keshavarz Blvd.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Khadijeh Otadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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

Yes - There is 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

kinds of treatment and results

When the data will become available and for how long

After publishing of data

To whom data/document is available

All

Under which criteria data/document could be used

For the best treatment

From where data/document is obtainable

Authors

What processes are involved for a request to access data/document

Email to authors

Comments