Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of telerehabilitation on physical and respiratory indicators of patients with chronic respiratory diseases

Protocol summary

Study aim

Studying the effect of telerehabilitation on physical and respiratory indices in patients with chronic respiratory disease

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 80 patients, using a random number table for randomization.

Settings and conduct

The present study is a clinical trial on patients with COPD referred to Masih Daneshvari Hospital in Tehran. In the control group, patients receive respiratory rehabilitation upon discharge from the hospital. In the intervention group, patients undergo pulmonary telerehabilitation upon discharge in addition to the respiratory rehabilitation program. This study is single-blinded, and the collected information is provided to the person evaluating the outcomes by removing the names and grouping of patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria included the patient's willingness to participate in the research project, COPD diagnosis based on a specialist physician's diagnosis, ability to perform rehabilitation during the days of hospitalization, and exclusion criteria included active cancer, advanced heart failure, advanced renal dysfunction, diabetes or uncontrolled blood pressure, inability of the patient to use a smartphone, and any disorder prohibiting rehabilitation exercises (musculoskeletal, neurological, etc.).

Intervention groups

In the intervention group, COPD patients who have undergone specialized treatment and rehabilitation at the center receive a username and password for the rehabilitation site upon discharge from the hospital and undergo telerehabilitation. In the control group, COPD patients receive only the recommended respiratory rehabilitation program.

Main outcome variables

Functional capacity, number of sit-stands, results of chronic obstructive pulmonary disease assessment questionnaires, and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210813052172N3**
Registration date: **2025-10-28, 1404/08/06**
Registration timing: **prospective**

Last update: **2025-10-28, 1404/08/06**
Update count: **0**

Registration date

2025-10-28, 1404/08/06

Registrant information

Name

Masoumeh ZoghAli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3662 4225

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masoumezoghali@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of telerehabilitation on physical and respiratory indicators of patients with chronic respiratory diseases

Public title

Investigating the effect of telerehabilitation on patients with chronic respiratory diseases

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient's willingness to participate in the research project COPD diagnosis based on a specialist doctor's diagnosis Ability to perform rehabilitation during hospital stay

Exclusion criteria:

Active cancer Advanced heart failure Advanced renal dysfunction Diabetes or uncontrolled blood pressure The patient's inability to use a smartphone Any disorder that prevents rehabilitation exercises (musculoskeletal, neurological, etc.)

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method, individual randomization unit, randomization tool: Random number table. For randomization, the Simple Randomization method is used using a random number table. For this purpose, two groups (A, B) are considered. We choose one of the rows of the random number table at will and we know that the numbers in each row will be between 0 and 9. Then we assign the numbers 0-4 to treatment A and the numbers 5-9 to treatment B. Suppose the numbers for the first row are as follows: 0, 5, 2, 7, 8, 4. Therefore, the number 0 is assigned to treatment A, the number 5 to treatment B, the number 2 to treatment A, ... Therefore, the first person receives treatment A, the second person receives treatment B ....

Blinding (investigator's opinion)

Single blinded

Blinding description

The clinical outcome assessor will not have access to patient grouping and will remain blinded throughout the study. Patients and therapists will not be blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Yemen St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2025-10-08, 1404/07/16

Ethics committee reference number

IR.SBMU.MSP.REC.1404.363

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44.9

ICD-10 code description

Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description

Functional capacity

Timepoint

Before and after rehabilitation

Method of measurement

Based on distance of six minute walk test

Secondary outcomes

1

Description

Total score of the Chronic Obstructive Pulmonary Disease Assessment Test (CAT)

Timepoint

Before and after rehabilitation

Method of measurement

Chronic obstructive pulmonary disease assessment test

(CAT)

2

Description
Quality of life
Timepoint
Before and after rehabilitation
Method of measurement
Chronic respiratory disease questionnaire (CRDQ)

3

Description
Quality of life
Timepoint
Before and after rehabilitation
Method of measurement
London chest activity of daily living (LCADL)

4

Description
Quality of life
Timepoint
Before and after rehabilitation
Method of measurement
Total score of St. George's questionnaire

Intervention groups

1

Description
Intervention group: In the intervention group, patients with COPD who have undergone specialized treatment and rehabilitation at the center will receive a username and password for the Masih Daneshvari Hospital rehabilitation site upon discharge from the hospital and will implement the pulmonary telerehabilitation program at home. After eight weeks, the patient will return to the hospital and be evaluated on an outpatient basis.
Category
Rehabilitation

2

Description
Control group: In the control group, patients with COPD who have undergone specialized treatment and rehabilitation at the center are discharged after receiving the recommended respiratory rehabilitation program including pursed lip breathing, diaphragmatic breathing, and sputum evacuation techniques. After eight weeks from discharge, patients are called back to the Pulmonary Rehabilitation Clinic of Masih Daneshvari Hospital.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Zahra Valizadeh
Street address
Masih danedvari hospital, darabad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Yemen St, Shahid Chamran Highway
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Maryam Sadat Mirenayat

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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Biotechnology

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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
No - There is not a plan to make this available