Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Functional Electrical Stimulation Intervention on Fatigue, Muscle Strength, Muscle Mass and Quality of Life in Older Adults with COVID-19

Protocol summary

Study aim

The effect of functional electrical stimulation intervention on fatigue, muscle strength, muscle mass and quality of life in older adults with COVID-19

Design

A randomized clinical trial study with parallel groups, Double-blinded on 40 patients, Randomization will be done simply by random numbers table.

Settings and conduct

This study is performed with the voluntary participations with COVID-19 at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences. The intervention group will receive functional electrical stimulation but the other group will receive sham functional electrical stimulation. In both groups, treatment sessions include 10 consecutive treatment sessions. To evaluate the effects of functional electrical stimulation, participants in both groups were evaluated before and after the intervention. Patients and evaluator are blind.

Participants/Inclusion and exclusion criteria

Elderly people with COVID-19 after hospital discharge; Age over 60 years؛ Obvious atrophy of the Quadriceps and Tibialis anterior muscles; Normal level of alertness ,orientation and responsiveness to verbal stimulus; To be willing to participate in the study

Intervention groups

The first group will receive functional electrical stimulation during 10 sessions of rehabilitation treatment. The second intervention group will receive sham functional electrical stimulation during 10 sessions of rehabilitation treatment.

Main outcome variables

fatigue; muscle strength; muscle mass; quality of life

General information

Reason for update

Acronym

COVID-19

IRCT registration information

IRCT registration number: **IRCT20201102049234N2**
Registration date: **2021-10-26, 1400/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-26, 1400/08/04**
Update count: **0**

Registration date

2021-10-26, 1400/08/04

Registrant information

Name

Mona Ramezani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3332 8502

Email address

mona.ramezani.sa@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Functional Electrical Stimulation Intervention on Fatigue, Muscle Strength, Muscle Mass and Quality of Life in Older Adults with COVID-19

Public title
The Effect of Functional Electrical Stimulation Intervention in Treatment of Older Adults with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Elderly People with COVID-19 After Hospital Discharge Age Over 60 Years Obvious Atrophy of the Quadriceps and Tibialis Anterior Muscles Normal Level of Alertness ,Orientation and Responsiveness to Verbal Stimulus To Be Willing to Participate in the Study

Exclusion criteria:
Pregnancy Known or Suspected Malignancy in the Lower Limb Body Mass Index Equal or Greater than 35 Kilogram Per Square Meter Conditions Preventing Electrical Stimulation Treatment for Example Deep Vein Thrombosis and Rhabdomyolysis Skin Lesions at the Site of Electrical Stimulation Diagnosis of Alzheimer's Disease, Degenerative Disease and Polyneuropathy Conditions Preventing Outcome Assessment for Example Amputation or Inability to Walk Presence of an Implanted Cardiac Pacemaker or Defibrillator

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with a random number table such that each person is given a code and they are written in a table. We select one place from the table in a blinded manner. Then we select 12 numbers smaller than the selected number in the same row. The same would be true for the treatment and control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher will be blind to the intervention using the research assistant and he/she is absent in the treatment room. The outcome evaluator will vary with the researcher and research data be given him with code and is unaware of the participants intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Headquarters of Semnan University of Medical Sciences, Basij Blvd., Semnan

City
Semnan

Province
Semnan

Postal code
3514799442

Approval date
2021-09-28, 1400/07/06

Ethics committee reference number
IR.SEMUMS.REC.1400.153

Health conditions studied

1

Description of health condition studied
Coronavirus disease (COVID-19)

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Fatigue

Timepoint
Before the intervention and after the end of intervention

Method of measurement
Chalder fatigue questionnaire

2

Description
Muscle Strength

Timepoint
Before the intervention and after the end of intervention

Method of measurement
Biofeedback pressure device

3

Description
Muscle Mass
Timepoint
Before the intervention and after the end of intervention
Method of measurement
Ultrasonographic device

4

Description
Quality of Life
Timepoint
Before the intervention and one month after the start of intervention
Method of measurement
WHOQOL-BREF questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group will receive functional electrical stimulation during 10 sessions of rehabilitation treatment. The patient will sit on a chair. FES will apply bilaterally using an electrical stimulator (710 P-plus, Iran) with pairs of electrodes (10 × 5 cm) placed transversally on the quadriceps muscle (5 cm below the inguinal crease and 5 cm above the patella). The stimulation protocol consists in the application of symmetrical biphasic rectangular pulses with a frequency of 30 Hz (pulse duration: 400 µs). The total duration of the FES session is 30 minutes. Thus eliciting a total of 90 evoked contractions per day. Stimulation intensity will adjust daily by the physical therapist to elicit a visible twitch in each muscle. The maximal stimulation intensity will record for each session and considered as a surrogate marker of FES dose. The patient will sit on a chair. FES will apply bilaterally using an electrical stimulator with pairs of electrodes (10 × 5 cm) placed transversally on the anterior tibialis muscle. One electrode will place over the motor point of the TA muscle and the other will place immediately below the belly of the muscle. FES will be apply for 20 minutes (pulse duration µs) with a frequency of 50 Hz.
Category
Treatment - Devices

2

Description
Control group: The second intervention group will receive sham functional electrical stimulation during 10 sessions of rehabilitation treatment. Sham FES will follow the same procedures, but the device will switch on only for the initial 20 seconds, with the current then diminish to zero. The patients will inform of the possibility of feeling a slight initial tingling that would either diminish, disappear or continue during the 20-minute session.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Semnan unuversity of medical science, Neuromuscular Rehabilitation Research Center
Full name of responsible person
Fariba Ramezani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Semnan 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
Semnan University of Medical Sciences
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Fariba Ramezani
Position
Master Student of Physiotherapy
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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