

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigation the effect of environmental exercises (physical and virtual reality environment) on the brain reorganization, molecular parameters and behavioral functions (cognitive and motor) in the chronic stroke patients

Protocol summary

Study aim

1. Investigation the effect of environmental exercises (physical and virtual reality environment) on the brain reorganization, brain-derived neurotrophic factor and cognitive and motor functions in the chronic stroke 2. Investigating the interactive effect of the type of environmental exercises (physical environment and virtual reality environment) and Atorvastatin on the brain reorganization, brain-derived neurotrophic factor and cognitive and motor functions in the chronic stroke

Design

Three parallel group, 12 people per group, simple non-probability sampling, double blind, pre & post treatment assessment, 3 month follow up, 3 month cognitive-motor dual task training

Settings and conduct

National Molecular- Cellular and Imaging Laboratories, Clinics and Research Centers of Therapy. Blind blind, unaware of evaluators and patients of how to group patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: first stroke The last 6-24 months since the lesion 65-35 years The ability to walk at least 10 m without auxiliary equipment No history of falling over the past 6 months Acceptable level of cognitive performance No hemi neglect No history of other neurological problems, orthopedics and upper limb surgeries involved Criteria for Receiving and taking Atorvastatin Damage to the middle cerebral artery as a cause of stroke Ability to read and write Understandable speech No vision problems exclusion criteria: Falling during tests and exercises Failure to cooperate properly and correct implementation of the instructions

Intervention groups

1. not receive any exercise 2. take exercises in the physical environment. 3. receive exercises in the virtual

reality environment.

Main outcome variables

Balance and Mobility; Working memory; Response Inhibition; executive Function; Serum Level of Brain-derived Growth Factor; Brain Volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180619040156N1**

Registration date: **2018-10-20, 1397/07/28**

Registration timing: **prospective**

Last update: **2018-10-20, 1397/07/28**

Update count: **0**

Registration date

2018-10-20, 1397/07/28

Registrant information

Name

Sohaila Fallah

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-29, 1397/08/07

Expected recruitment end date

2019-06-24, 1398/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of environmental exercises (physical and virtual reality environment) on the brain reorganization, molecular parameters and behavioral functions (cognitive and motor) in the chronic stroke patients

Public title

Investigation the effect of cognitive and motor exercises on improving the performance of chronic stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Experience the first stroke Passed for 6-24 months after lesion Having ages between 35-65 years Ability to walk at least 10 meters without auxiliary equipment No history of falling over the past 6 months according to the patient's own report Having an acceptable level of cognitive performance means a score of over 24 in the Mini Mental Status Examination (MMSE) test. Not having hemi neglect using the Star Cancellation test Not having any history of other neurological problems, orthopedics and upper limb surgeries involved according to medical records, patient's or patient's report or observation of the examiner Having the criteria for receiving and consuming Atorvastatin drug on the basis of a neurologist's diagnosis Central cerebral artery injury as the cause of stroke Ability to read and write Having understandable speech The lack of vision problems has not been resolved

Exclusion criteria:

Falling during assessments and exercises Failure to cooperate properly and correct implementation of the instructions during the tests and exercises.

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **3**
More than 1 sample in each individual
Number of samples in each individual: **12**
Sampling are done in an unpredictable way (convenience) and grouping is done randomly

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

trials are double-blind, which means that neither Data analyser nor the outcome assessors know which people are getting which treatments

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

Hemmat Highway . Iran University of Medical Sciences

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tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-09-29, 1397/07/07

Ethics committee reference number

ir.iums.REC.1397.150

Health conditions studied**1****Description of health condition studied**

chronic stroke

ICD-10 code

Z82.3

ICD-10 code description

Family history of stroke

Primary outcomes**1****Description**

Balance and upper and lower extremity mobility assessments (behavioral tests)

Timepoint

Before interventions, immediately after intervention, 3 months after intervention

Method of measurement

Timed up go test, functional reach test, berg test, fugl

meyer test

2

Description

Cognitive Assessments (Behavioral Tests)

Timepoint

Before interventions, immediately after intervention, 3 months after intervention

Method of measurement

Wechsler test, Wisconsin test, Stroop test

3

Description

serum levels of brain-derived growth factor (molecular laboratory tests)

Timepoint

Before interventions, immediately after intervention, 3 months after intervention

Method of measurement

Brain derived neurotrophic factor analysis

4

Description

structural changes in various brain regions (laboratory imaging test)

Timepoint

Before interventions, immediately after intervention, 3 months after intervention

Method of measurement

magnetic resonance imaging

Secondary outcomes

1

Description

Changes in fear of falling

Timepoint

Before and after intervention and 3 months after intervention

Method of measurement

Activities-based balance confidence scale (ABC)

2

Description

Quality of life score

Timepoint

Before and after intervention and 3 months after intervention

Method of measurement

Short Form (36) Health Survey (SF-36)

3

Description

changes in fatigue levels

Timepoint

Before and after intervention and 3 months after intervention

Method of measurement

Multidimensional Fatigue Symptom Inventory-Short Form

Intervention groups

1

Description

Intervention group: Stroke patients receiving cognitive-motorized physical training in the physical environment and rehabilitation routine interventions

Category

Rehabilitation

2

Description

Intervention group: Stroke patients undergoing cognitive-motor-physical exercises in the virtual reality environment and rehabilitation routine interventions

Category

Rehabilitation

3

Description

Control group: Stroke patients receiving only rehabilitation routine interventions

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Mohammad Taghi Jaghatai

Street address

No. 110, Valdi Alley, Valiasr Ave, Firoozgar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malekoti

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Soheila Fallah

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Rehabilitation management

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

In order to be trusted in the patient's personal information, their data is encoded and then shared with other researchers.

When the data will become available and for how long

After the completion of the design and documentation of the obtained data, the information is provided to the researchers. It takes about 1 year to complete this documentation.

To whom data/document is available

All researchers in the field of neurological diseases will have access to this information

Under which criteria data/document could be used

Other researchers can access the information after submitting an abstract of their research plan.

From where data/document is obtainable

by Email sohailafallah66@gmail.com

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

By submitting the abstract of the project and by email, it is provided

Comments