Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation the effect of environmentàl 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 environmentàl 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 environmentàl 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)

Phone

+98 21 8670 4606

Email address

fallah.s@tak.iums.ac.ir

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
City
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
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2687
Email
joghataei@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Kazem Malekoti

Street address
Hemat Highway, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2687
Email
joghataei@iums.ac.ir

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
Street address
Hemat Highway, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2687
Email
fallah.s@tak.iums.ac.ir

Person responsible for scientific 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
Street address
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Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2687
Email
fallah.s@tak.iums.ac.ir

Person responsible for updating data

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
Street address
Hemat Highway, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
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Phone
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Email
fallah.s@tak.iums.ac.ir

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