

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effectiveness of neurofeedback and cognitive rehabilitation on balance and cognitive function in the elderly

Protocol summary

Study aim

The effectiveness of neurofeedback and cognitive rehabilitation on balance and cognitive functions in the elderly

Design

A concealed, randomized trial with blinded data investigator. A total of 40 individuals were chosen, and then they were randomly divided into 3 groups: neurofeedback groups, cognitive rehabilitation treatments, combination of both and control group.

Settings and conduct

Before and after interventions, the balance of participants in all three groups was assessed using the Timed Up and Go test, the Berg Balance Scale, and the Tinetti balance score and cognitive function in each group was assessed using Mini-mental state examination and Montreal Cognitive Assessment. After neurofeedback training and Captain Log cognitive rehabilitation and combined them, post-test was taken from all four groups. The place of conducting the trial is the Movafaghiat Clinic. Data for all subjects were obtained, by an investigator who was blinded to the treatment allocation.

Participants/Inclusion and exclusion criteria

Those elderly 65-74 years old who are able to walk independently without assistive devices, do not have cranial implants and have no history of attending psychotherapy and neurofeedback sessions are recruited into this study. Subjects with a definite diagnosis of neurological disorders, orthopedic disorders and cardiovascular and respiratory diseases, as well as those who suffer from visual or vestibular impairment or take medications that cause balance disorders and, absent during intervention sessions, are excluded from the study

Intervention groups

Neurofeedback is a method that assists subjects to control their brain waves consciously. The intervention in the cognitive therapy group includes Captain Log, which is a software to rehabilitate and enhance cognitive

functions.

Main outcome variables

Balance, Cognitive Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211228053555N1**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name

Fatemeh Bahramian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0083

Email address

fbahramian69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effectiveness of neurofeedback and cognitive rehabilitation on balance and cognitive function in the elderly

Public title
Effect of the neurofeedback and cognitive rehabilitation in the elderly

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Those elderly who do not have cranial implants Those elderly who are able to walk independently without assistive devices Those elderly who have conscious consent to participate in research Those elderly who have no history of attending psychotherapy and neurofeedback sessions
Exclusion criteria:
old people with a definite diagnosis of neurological disorders, orthopedic disorders and cardiovascular and respiratory diseases old people with a visual or vestibular impairment, or those who taking medications which cause balance problems the elderly who had a score below 7 on the Brief cognitive test Personal reluctance to continue treatment

Age
From **65 years** old to **74 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Using sealed envelopes participants were randomly assigned to one of the three groups of study. The envelopes received numbers in advance (coded as 1, 2, and 3), and were opened sequentially, only after the participant's name was written on the appropriate envelope. Random allocation sequences remained concealed from those enrolling participants into the study to minimize the effects of bias.

Blinding (investigator's opinion)
Single blinded

Blinding description
Data for all subjects were obtained, by an investigator who was blinded to the treatment allocation

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address

kodakyar Ave, Daneshjoo Blvd, Evin, Tehran, University of Social Welfare and Rehabilitation Science

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2021-12-27, 1400/10/06

Ethics committee reference number

IR.USWR.REC.1400.230

Health conditions studied

1

Description of health condition studied

The elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cognitive function

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Mini-Mental State Examination, Montreal Cognitive Assessment

2

Description

Balance

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Timed Up and Go test, the Berg Balance Scale (BBS)

Secondary outcomes

1

Description

Risk of falling

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Tinetti balance score

Intervention groups

1

Description

Intervention group1: Neurofeedback Neurofeedback therapy involve 16 sessions, with two sessions per week. Neurofeedback training will be conducted using neurofeedback devices with Procomp hardware (Ver.0.5,) and Biography software produced by TAT Technologies Company (Thought Technology Ltd, Canada The method of electrode placement in this protocol is that the active electrode (0.01 reference electrode) will be placed on (the cerebellum) and the grand electrode will be placed on the right ear. Then, in the intervention phase, animation will present to them. As the brain waves of the elderly move away from the intended target (ie, increasing the theta wave and decreasing the beta waves), the animation will stop. To replay the animation, the elderly have to change their brain waves in the direction of the intended target.

Category

Rehabilitation

2

Description

Intervention group2: Cognitive rehabilitation In this study, Captain Log cognitive rehabilitation treatment is performed in 16 sessions, 2 times a week for 60 minutes each time. The Captain Log program is one of the software programs designed by Train Brain in the United States to rehabilitate and enhance cognitive functions. This set has 2000 different programs and assignments and includes basic cognitive skills and superior skills. Also, this software set has three levels: simple, medium and difficult, which are determined according to the subject's condition.

Category

Rehabilitation

3

Description

Intervention group 3: Neurofeedback + Cognitive Neurofeedback therapy In total, this group has 4 treatment sessions per week, including two neurofeedback sessions and two cognitive therapy sessions. Neurofeedback therapy involve 16 sessions, with two sessions per week. Captain Log cognitive rehabilitation treatment is performed in 16 sessions, 2 times a week for 60 minutes each time..

Category

Rehabilitation

4

Description

Control group: This group does not receive treatment. Only every week their conditions are checked by phone.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Movafaghiyat clinic

Full name of responsible person

Seyed Abolfazl Mousavi

Street address

No. 7, Shariati Street, Between Mirdamad and Zafar, Falsafi Alley, baran Building

City

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Postal code

1985713871

Phone

+98 919 300 3160

Email

seyed.abalfazl@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

seyed abolfazl mousavi

Street address

kodakyar Ave, daneshjo Blvd, Evin, Tehran, university of social welfare and rehabilitation sciences

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Email

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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

University of social welfare and rehabilitation 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**

Movafaghiyat Clinic

Full name of responsible person

Seyed Abolfazl Mousavi

Position

Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

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No. 7, Baran Building , Falsafy Alley, Between Mirdamad and Zafar Ave, Shariati St, Tehran Town.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Movafaghiyat clinic

Full name of responsible person

Seyed Abolfazl Mousavi

Position

Psychologist

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Fatemeh Bahramian

Position

Student

Latest degree

Master

Other areas of specialty/work

Rehabilitation

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Demographic information and information on the main outcome

When the data will become available and for how long

Start of access period from 1401

To whom data/document is available

Researchers working in academic institutions and clinics

Under which criteria data/document could be used

Use for further research and review articles

From where data/document is obtainable

Seyed Abolfazl Mousavi

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

Two weeks to review the request and check the purpose of receiving the data

Comments

Because the condition we are studying is not a disease,

we leave the ICD-10 code and ICD-10 code description fields empty according to your guideline.