Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the Effectiveness of Cognitive Behavioral Therapy Combined with Transcranial Direct Current Stimulation over dorsolateral prefrontal cortex on Fear of Falling and Social Frailty in Older Adults with Fear of Falling

Protocol summary

Study aim
Evaluating the Effectiveness of Cognitive Behavioral Therapy Combined with Transcranial Direct Current Stimulation over dorsolateral prefrontal cortex on Fear of Falling and Social Frailty in Older Adults with Fear of Falling

Design
A clinical trial with a control group, double-blind, single-center trial, randomized, 30 participants in 2 groups of 15 people.

Settings and conduct
Elderly people with a fear of falling - Neuromuscular Rehabilitation Research Center

Participants/Inclusion and exclusion criteria
Elderly people aged 60 to 75 living in Semnan city Inclusion criteria: Age 60 to 75 years; Living in Semnan city; Having a fear of falling in the past year; Absence of severe neurological or psychiatric conditions that would prevent participation in the intervention (such as advanced dementia or severe movement disorders); Adequate cognitive ability to answer questionnaires. Exclusion criteria: Absence from more than one meeting; Having acute or chronic illnesses (such as epilepsy, metal implants in the head, or uncontrolled cardiovascular disease); Taking medications that negatively affect cognitive function or balance (psychotropic drugs and opioid analgesics); A history of recent surgery or injury that affects balance.

Intervention groups
Intervention group: In this group, according to the protocol, patients receive cognitive-behavioral therapy(CBT) exercises along with transcranial direct current stimulation(tDCS) with an intensity of approximately 2 mA for 20 minutes on the dorsolateral prefrontal cortex(DLPFC) for 4 weeks, 2 sessions per week. Control group: In this group, according to the protocol, patients receive cognitive-behavioral therapy(CBT) exercises along with unreal transcranial direct current stimulation(tDCS) for 4 weeks, 2 sessions per week.

Main outcome variables
Fear of falling; The level of social vulnerability of the elderly; Functional balance;

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151228025732N85**
Registration date: **2026-08-16, 1405/05/25**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-16, 1405/05/25**
Update count: **0**

Registration date
2026-08-16, 1405/05/25

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

Country
Iran (Islamic Republic of)

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+98 23 3345 1336

Email address
are20935@semums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-06, 1405/05/15
Expected recruitment end date
2026-11-06, 1405/08/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the Effectiveness of Cognitive Behavioral Therapy Combined with Transcranial Direct Current Stimulation over dorsolateral prefrontal cortex on Fear of Falling and Social Frailty in Older Adults with Fear of Falling

Public title
Evaluating the Effectiveness of Cognitive Behavioral Therapy Combined with Transcranial Direct Current Stimulation over dorsolateral prefrontal cortex on Fear of Falling and Social Frailty in Older Adults with Fear of Falling
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 60 to 75 years Living in Semnan city Having a fear of falling in the past year Absence of severe neurological or psychiatric conditions that would prevent participation in the intervention (such as advanced dementia or severe movement disorders) Adequate cognitive ability to answer questionnaires
Exclusion criteria:
Absence from more than one meeting Having acute or chronic illnesses (such as epilepsy, metal implants in the head, or uncontrolled cardiovascular disease) Taking medications that negatively affect cognitive function or balance (psychotropic drugs and opioid analgesics) A history of recent surgery or injury that affects balance
Age
From **60 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 2). It will be done based on computer assisted coding.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding of the analyst, the outcome evaluator and the participant (double-blind) is done so that the groups are defined as A and B for the patients and provided to the analyst and the outcome evaluator so they do not know about the grouping method.
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
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2026-06-22, 1405/04/01
Ethics committee reference number
IR.SEMUMS.REC.1405.051

Health conditions studied

1

Description of health condition studied
Fear of falling
ICD-10 code
F40.233
ICD-10 code description
Fear of injury

Primary outcomes

1

Description
Fear of falling
Timepoint
Before the intervention, immediately after the intervention, and one month after the intervention.
Method of measurement
Using the Functional Efficacy in the Elderly Questionnaire (FES-I)

2

Description
The level of social vulnerability of the elderly
Timepoint
Before the intervention, immediately after the intervention, and one month after the intervention.
Method of measurement
Using the Social Frailty Questionnaire (SFS-8)

3

Description
Functional balance
Timepoint
Before the intervention, immediately after the intervention, and one month after the intervention.
Method of measurement
Berg Balance Scale (BBS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, according to the protocol, patients receive cognitive-behavioral therapy (CBT) exercises along with transcranial direct current stimulation (tDCS) with an intensity of approximately 2 mA for 20 minutes on the dorsolateral prefrontal cortex (DLPFC) for 4 weeks, 2 sessions per week.
Category
Rehabilitation

2

Description
Control group: In this group, according to the protocol, patients receive cognitive-behavioral therapy (CBT) exercises along with unreal transcranial direct current stimulation (tDCS) for 4 weeks, 2 sessions per week. This is for comparison with the intervention group only.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Neuromuscular Rehabilitation Research Center
Full name of responsible person
Fatemeh Ehsani
Street address
Neuromuscular Rehabilitation Research Center, Qods Blvd, Mashahir Aven.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Majid Eslami
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Semnan University of Medical Sciences, Basij Blvd, Semnan
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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
Full name of responsible person
Fatemeh Ehsani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Position
Student

Latest degree
Master

Other areas of specialty/work
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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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