Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

A Comparative Study on the effect of transcranial Direct Current Stimulation (tDCS) and Light Therapy (tLT) on the balance status of older adults

Protocol summary

Study aim

1) Determine the effectiveness of tDCS intervention on static balance status of the elderly 2) Determine the effectiveness of tLT intervention on static balance status of the elderly 3) Determine the effectiveness of tDCS intervention on the dynamic balance status of the elderly 4) Determine the effectiveness of tLT intervention on the dynamic balance status of the elderly 5) Determine the effectiveness of tLT intervention on attentional function in the elderly 6) Determine the effectiveness of tDCS intervention on attentional function in the elderly 7) Comparison of the effectiveness of tDCS intervention with tLT intervention on static elderly balance index 8) Comparing the effectiveness of tDCS intervention with tLT intervention on dynamic balance index in the elderly 9) Comparison of the effectiveness of tDCS intervention with tLT intervention on elderly attentional performance status

Design

Randomised controlled trial, parallel group, two intervention groups (intervention with tDCS, tLT), randomized

Settings and conduct

Samples are also selected by visiting the senior citizen friendly centers of Tabriz (6 centers) and inviting all the elderly.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age 65 and older 2. Having a history of falling 3. Willingness to participate in the research Exclusion criteria: 1. During the intervention, severe and acute illnesses including neuromuscular and motor disorders, visual and auditory and cognitive impairment, cardiovascular disease. 2. Elderly people who do not wish to continue their research. 3. Brain and nerve diseases such as epilepsy and seizures that increase the risk of irritation. 4. Any metal implants near the electrode junction 5. Any electrical device (such as a pacemaker) in the elderly's body.

Intervention groups

Sham group Intervention with tDCS Intervention with tLT

Main outcome variables

Balance and attention

General information

Reason for update

Acronym

transcranial Direct Current Stimulation (tDCS)
transcranial Light Therapy (tLT)

IRCT registration information

IRCT registration number: **IRCT20171031037124N2**
Registration date: **2020-04-04, 1399/01/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-04, 1399/01/16**
Update count: **0**

Registration date

2020-04-04, 1399/01/16

Registrant information

Name

shahab papi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0004

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-04-03, 1399/01/15
Expected recruitment end date
2020-07-05, 1399/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparative Study on the effect of transcranial Direct Current Stimulation (tDCS) and Light Therapy (tLT) on the balance status of older adults

Public title
The effect of transcranial Direct Current Stimulation (tDCS) and Light Therapy (tLT) on the balance status
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 65 and older Having a history of falling (once or more than once in the last year) Willingness to participate in the research Lack of neuromuscular and motor disorders, limb fractures, structural defects Lack of medical records based on cognitive impairment No movement restriction in the pelvis, knee and ankle Natural or modified natural appearance No use of hearing aids and cochlear implants No cardiovascular disease
Exclusion criteria:
Ability to walk independently Ability to communicate
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Samples were selected by available method and assigned to study groups using randomized block design with volume 3. At the design stage of the study, it is not possible to control for confounding variables in the blocking method, but at the data analysis stage, the effect of potential confounders (such as the presence or absence of history of receiving different balance exercises in the intervention and sham groups due to being older). The person and the likelihood of receiving previous interventions (such as physiotherapy and occupational therapy in cases such as knee osteoarthritis) will be adjusted. The random sequence is generated using RAS software.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Faculty of Health, Tabriz University of Medical Sciences, Attar Neyshabouri St., Golghasht St., Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2020-01-06, 1398/10/16
Ethics committee reference number
IR.TBZMED.REC.1398.1054

Health conditions studied

1

Description of health condition studied
Balance and attention
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Balance and attention
Timepoint
Measurement of balance and attention status at the beginning of the study, after the intervention and one week after the intervention
Method of measurement
One leg stand test (Stork) as a static balance task and TUG as a dynamic balance test. PGNG attentional test to check attentional

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1 (tDCS): In this study, induction of 1 mA direct current with a density between 0.029 and 0.08 for twenty minutes over five consecutive sessions on the primary motor cortex (M1) was used. This region was identified by the International EEG System 10-20 and the anode was considered as the active pole.
Category
Prevention

2

Description
Intervention group 2 (tLT): At this stage, the light is transmitted continuously by the NIR wave projector, with a specific wavelength of 850 nm, with a power of 260 mW / cm2 and an energy density of 4 J / cm2 over the desired regions.
Category
Prevention

3

Description
Control group: This group of seniors will receive both tDCS and tLT interventions.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Babaei Health Center
Full name of responsible person
Dr. Behnaz Hashemi
Street address
Shahid Babaei Street One, Flight Town, tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Mohammad Samiei
Street address
Tabriz University of Medical Sciences,Golgasht Street, Tabriz-Iran
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+98 41 3334 4280
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samieim@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
shahab papi
Position
student
Latest degree
Ph.D.
Other areas of specialty/work
Geriatrics
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Associate professor

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Neuroscience

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Person responsible for updating data

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Latest degree
Ph.D.

Other areas of specialty/work
Geriatrics

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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
Not applicable

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