

Effect of brain stimulation along with gait training in improving life participation among hemiplegia patients

Submission date 26/12/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/01/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/01/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The subacute phase of stroke is critical for rehabilitation, yet many patients continue to experience substantial disabilities and decreased quality of life. Rehabilitation approaches like gait training or neuromodulation treatments result in significant improvements. However, combining neuromodulation with a physical activity intervention had more significant results in recent studies. Hence this study aimed to find out whether gait-oriented therapy augmented by transcranial direct current stimulation (tDCS) promotes functional recovery of neurological and muscular impairments.

Who can participate?

Subacute stroke patients aged 18–80 years

What does the study involve?

Participants were randomly allocated to one of two groups. The study experimental group was given tDCS (2 mA, 20 minutes, 3 days per week for 4 weeks) along with gait-oriented motor training, while the control group received motor training alone.

What are the possible benefits and risks of participating?

The possible benefits were improved function, balance, gait, and quality of life, and there were no risks for the participants.

Where is the study run from?

King Khalid University (Saudi Arabia)

When is the study starting and how long is it expected to run for?

August 2023 to May 2024

Who is funding the study?

King Salman Center for Disability Research (Saudi Arabia)

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Effects of transcranial direct current stimulation combined with gait-oriented motor training on disability, quality of life, and motor functions in individuals with sub-acute stroke: a randomized controlled trial

Acronym

tDCSGOMT

Study objectives

This research will contribute to advancing the understanding and use of combined neuromodulation and motor training methods in stroke rehabilitation.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 19/12/2023, Institutional Review Board of the Deanship of Scientific Research, King Khalid University (Deanship of Scientific Research, King Khalid University, Abha, 61421, Saudi Arabia; +966 (0)17 2418645; ecm@kku.edu.sa), ref: ECM#2023-3304

Study design

Interventional single-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

Study type(s)

Quality of life, Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Sub acute stroke

Interventions

A curated protocol with tDCS and gait-oriented motor training was applied to the intervention group. The control group received only gait-oriented motor training. To ensure equal distribution of the groups in the study, a computer-generated block random allocation sequence was used. To maximize protocol compliance, both groups were supervised by trained rehabilitation therapists. In both groups, sessions were held for 1 hour, 3 days a week for 4 weeks.

Intervention Type

Other

Primary outcome measure

Measured before the beginning of the study intervention, after 4 weeks of the study intervention, and after 3 months of post-intervention:

1. Disability measured with the World Health Organization Disability Assessment Schedule
2. Quality of life assessed with the Stroke Impact Scale

Secondary outcome measures

Measured before the beginning of the study intervention, after 4 weeks of the study intervention, and after 3 months of post-intervention:

1. Motor function measured with the Fugl-Meyer Assessment for Lower Extremities
2. Balance evaluated by the Berg Balance Scale
3. Functional mobility was assessed by the Timed Up and Go test

Overall study start date

15/08/2023

Completion date

31/05/2024

Eligibility

Key inclusion criteria

1. Medically stable adults aged 18–80 years
2. Experienced a first-ever ischemic or hemorrhagic stroke
3. Reduced motor control in the lower extremities
4. Mini-Mental State Examination for cognitive function score ≥ 24

Participant type(s)

Patient

Age group

Senior

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

62

Total final enrolment

62

Key exclusion criteria

1. Presence of severe spasticity (Modified Ashworth Scale score >3)
2. Currently participating in another rehabilitation program
3. Significant comorbidities that might cause exclusion from participation (severe cardiovascular disease or orthopedic conditions)
4. tDCS contraindications such as implanted electronic devices or a history of epilepsy

Date of first enrolment

01/01/2024

Date of final enrolment

01/05/2024

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

Program of Physical Therapy, Department of Medical Rehabilitation Sciences

Building Number W4

College of Applied Medical Sciences

King Khalid University

Al Fara

Abha

Saudi Arabia

61421

Sponsor information

Organisation

King Salman Center for Disability Research

Sponsor details

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Sponsor type

Research organisation

Website

<https://www.kscdr.org.sa/en>

ROR

<https://ror.org/01ht2b307>

Funder(s)

Funder type

Research organisation

Funder Name

King Salman Center for Disability Research

Alternative Name(s)

, KSCDR

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

Saudi Arabia

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed international journal

Intention to publish date

01/05/2025

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication