ISRCTN62197971 https://doi.org/10.1186/ISRCTN62197971

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

Registration date
12/01/2025

Overall study status
Completed

Last Edited
08/01/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Dr Jaya Shanker Tedla, jtedla@kku.edu.sa

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Jaya Shanker Tedla

ORCID ID
https://orcid.org/0000-0002-2876-4227

Contact details
S-058, Building Number M03
College of Applied Medical Sciences
King Khalid University
Al Fara
Abha
Saudi Arabia
61421
+966 (0)538901083
jtedla@kku.edu.sa

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Quality of life, Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
18 years

Upper age limit
80 years

Sex
All

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

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

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