Postural feedback combined with Non-invasive transcranial direct current stimulation in patients with stroke, a randomized controlled clinical trial.

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POTENTIAL will be the first phase II RCT to assess the effects of combined cerebellar tDCS and VR-PFT in terms of outcomes at the level of body functions, activities and participation, as well as brain reorganization post stroke. Ultimately,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON47155

Source
ToetsingOnline

Brief title
POTENTIAL RCT

Condition

- Central nervous system vascular disorders

Synonym
Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: standing balance, Stroke, tDCS

Outcome measures

Primary outcome

Berg Balance scale, assessing functional balance performance.

Secondary outcome

(10mwt) 10 meter walk test, (FES) fall efficacy scale, (FM-MS) Fugl-Meyer Motor Score, (MI) motricity index, (EmNSA) Erasmus modification of the Nottingham sensory assessment, (BI) barthel index, (NEADL) Nottingham extended activity of daily living,(O-LCT) O letter cancelation task (SIS) stroke impact scale; assessing function, activity and participation.

Postural balance control parameters and spatial-temporal changes in functional cortical networks and connectivity.

Study description

Background summary

Postural instability, balance problems and subsequent falls are very common in patients with a stroke and strongly associated with future functional recovery. The early period after stroke is characterized by a critical time window of neuroplasticity. Postural feedback training (PFT) is a common rehabilitative therapy to improve standing balance control in patients with stroke, and is equally effective to improve balance control as usual care. Studies suggest that a positive, reproducible effect on motor learning may be achieved by simultaneous non-invasive transcranial direct current stimulation (tDCS) and motor training. A combination of early applied tDCS and PFT by modern virtual reality techniques (VR-PFT) may therefore improve balance in patients with stroke to a level unattained by VR-PFT alone. To date, non-invasive brain stimulation has not been applied in combination with modern balance training

techniques in stroke.

Study objective

POTENTIAL will be the first phase II RCT to assess the effects of combined cerebellar tDCS and VR-PFT in terms of outcomes at the level of body functions, activities and participation, as well as brain reorganization post stroke. Ultimately, findings will be important for improving rehabilitation services post stroke, allowing clinicians to apply new motor learning therapies more effectively in the future.

Study design

double-blind controlled intervention study.

Intervention

A three week VR-PFT intervention applied five days per week for one hour will be started within five weeks post-stroke, in addition to usual care. This intensive training will be given in order to test if VR-PFT in combination with cerebellar tDCS is more effective in improving standing balance than VR-PFT alone. Patients train in groups and go along workstations consisting of a virtual reality setup in which instantaneous visual feedback is given regarding centre of gravity or trunk movements during several balance tasks. These tasks requiring active control of body posture and equilibrium in a virtual environment. The training program is individually tailored and progressive with systematic increments in task difficulty. tDCS will be simultaneously applied with the training during the first 25 minutes of each session using a pre-programmed stimulation paradigm. Sham-tDCS starts with a ramped stimulation of 30s followed by 0 mA current without the subject knowing this. Measurements: Clinical, posturographic and neurophysiological measurements will take place at baseline and three, five and twelve weeks after the start of the intervention. Measurements including preparation will take about 1,5 hour.

Study burden and risks

Patients will receive group therapy sessions of one hour, five times a week for three weeks at the rehabilitation site where they reside or receive outpatient therapy. Usual care will continue during the intervention. Measurements including preparation will take approximately 1,5 hour and take place at the same rehabilitation facility. The measurements will be carried out four times: at baseline, three, five and twelve weeks after the start of the intervention. Risks associated with the treatment are negligible or reduced with the exclusion criteria. Improvement of functional balance performance is expected for both groups but to a greater extent in the intervention group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) A postural balance deficit as determined by a Berg Balance Scale score of 50 or lower
2) a first ever ischemic lesion in the territory of the middle cerebral artery (MCA) as verified by CT of MRI scan

Exclusion criteria

1) Any metallic implants (pacemaker etc.)
2) Orthopedic limitations that interfere with the study
3) Cranial bone defects
4) History of epileptic seizures
5) Signs of depression (Hospital Anxiety and Depression Scale, HADS, sub score D >10)

6) Insufficient cognitive function (Mini Mental State Examination, MMSE < 19)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-10-2016
Enrollment:	56
Type:	Actual

Medical products/devices used

Generic name:	transcranial direct current stimulation (tDCS)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-01-2016
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29432
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52021.029.15
OMON	NL-OMON29432

Study results

Date completed:	01-11-2019
Actual enrolment:	20

Summary results

Trial is onging in other countries