Improving standing balance after stroke with tDCS and postural feedback therapy.

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VR-based postural feedback training combined with non-invasive cerebellar tDCS is more effective as compared to the same balance training program with sham-stimulation in improving postural balance control parameters and standing balance performance...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29432

Bron
NTR

Verkorte titel
POTENTIAL RCT

Aandoening

tDCS, stroke, CVA, postural feedback therapy, balans

Ondersteuning

Primaire sponsor: VU medical center
Overige ondersteuning: Hersenstichting Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Berg Balance scale, assessing functional balance performance.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

VR-based postural feedback training combined with non-invasive cerebellar tDCS is more effective as compared to the same balance training program with sham-stimulation in improving postural balance control parameters and standing balance performance in sub-acute stroke patients

Onderzoeksopzet

3 months

Onderzoeksproduct en/of interventie

A tree 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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) A postural balance deficit as determined by a Berg Balance Scale score of 50 or lower, 2) less than five weeks after a first ever cortical or subcortical ischemic lesion, excluding lesions of the cerebellum, 3) age ≥ 30, 4) written informed consent, 5) be able to stand for 30 seconds with minimal support 6) normal vision or corrected to normal with an optical aid, 7) able and sufficiently motivated to perform the required tests and intervention sessions.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Any Presence of metallic implants (pacemaker etc.) , pacemaker, intracranial electrodes, implanted defibrillators, cranial pathologies (e.g. holes, plaques) or any other prosthesis, 2)

orthopaedic limitations that interfere with the study, 3) not being able to communicate , 3) successful thrombolysis treatment (no clinical sequel of the stroke) , 4) No neurological disease or condition (except from the stroke) 5) Cranial bone defects, 6) history of epileptic seizures, 7) diagnoses bipolar or psychiatric disorder 8) signs of depression (Hospital Anxiety and Depression Scale, HADS, sub score D≥10) (Zigmond and Snaith 1983) 9) insufficient cognitive function (Mini Mental State Examination, MMSE < 19), 10) sensory impairments prior to the ischemic lesion (patients will be asked if they have a medical history of neuropathy), 11) diagnosed diseases of the vestibular system.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-09-2016
Aantal proefpersonen:	46
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-06-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47155
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5032
NTR-old	NTR5261
CCMO	NL52021.029.15
OMON	NL-OMON47155

Resultaten