Explaining plasticity after stroke

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EXPLICIT aims tot obtain better functional outcome by early intensive rehabilitation. Next to clinical tests to measure improvement in function, neuroplasticity is assessed by fMRI, TMS and haptic robots. The combination of clinical outcome measures...

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

Summary

ID

NL-OMON38065

Source
ToetsingOnline

Brief title
EXPLICIT

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZON MW

Intervention

Keyword: cerebrovascular accident, motor learning, neuroplasticity

Outcome measures

Primary outcome

Action Research Arm Test

focusing of cortical activity on the original physiological areas

bending of the trunk during the standard reaching task

velocity induced gain of the peripheral spinal reflex chain and reflex

modulation

Secondary outcome

Ashworth Score

Wolf Motor Function Test

Frenchay Arm Test

Motricity index

Brunnstrom Fugl Meyer arm/hand test

Nine Hole Peg Test

Erasmus MC Modification of the (revised) Nottingham Sensory Assessment

Stroke Impact Scale version 3.0

Nottingham Extended ADL

Motor Activity Log

O-Letter Cancellation Test

Barthel Index

Study description

Background summary

Prospective cohort studies show that about 80% of all stroke survivors have an upper limb paresis immediately after stroke. Only one third of all stroke patients will regain some dexterity, whereas well-researched evidence based therapies for an effective treatment of the upper limb are lacking.
However, the main claim of the literature is that functional recovery of the upper paretic limb is mainly defined within the first month post stroke and that rehabilitation services should be applied preferably within this time window of recovery. Furthermore, it is known that exercise-related interventions are most effective when they are applied intensively in a task-oriented way.

Study objective

EXPLICIT aims tot obtain better functional outcome by early intensive rehabilitation.
Next to clinical tests to measure improvement in function, neuroplasticity is assessed by fMRI, TMS and haptic robots. The combination of clinical outcome measures and neuro-imaging will serve as a template for understanding basic mechanisms of functional recovery after stroke.
EXPLICIT will provide an answer to the key question whether therapy induced improvements are due to either a reduction of basic motor impairment by neural repair or the use of behavioral compensation strategies.

Study design

2 randomized controled trials: 1 each for CIMT and EMG-neuromuscular stimulation compared to conventional therapy.

Intervention

Constrained Induced Movement Therapy
or
EMG-triggered Neuromuscular Stimulation
or
Conventional therapy

Study burden and risks

There are very little risks associated with participation, as none of the interventions or clinical measurements are invasive.
The proposed therapies have little to none known side-effects.
The safety standards for EEG are strictly followed.

The burden on the patients time will be 1,2 to 2,4 hours per week, depending on the trial they will be allocated to.

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

first-ever ischemic CVA, mono-or hemiparesis as defined by NIHSS, age between 18-80 year, able to communicate, able to sit without support, motivated to participate in an intensive rehabilitation programme for 3 weeks.

Exclusion criteria

treatment with rTPA, pacemaker or other metallic implants, previous existing orthopedic limitations of upper limb that would affect the results, botuline-toxine injections or medication that may influence upper limb function in past 3 months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO

Date:	28-06-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	22-01-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL21396.058.08