ULTRA-stroke.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27945

Source
NTR

Brief title
ULTRA-stroke

Health condition

Stroke, beroerte, neurorehabilitation, neurorevalidatie.

Sponsors and support

Primary sponsor: VU Faculty of Human Movement Sciences, VU University Medical Center, Department of Rehabilitation Medicine, MOVE, Rehabilitation Centre Amsterdam
Source(s) of monetary or material Support: MOVE Research Institute

Intervention

Outcome measures

Primary outcome

1. Action Research Arm test (ARAT);

2. Patterns of correlated cortical activity in original and contralateral target areas and changes in spectral power in specific frequency bands;

3. Neuromechanics, i.e. stiffness, motor function (paresis) and control (reflex gains and

modulation) around wrist joint;

4. Contribution of sources (feedforward, error correction, and fase entrainment) of interlimb interactions.

Secondary outcome

1. Motricity Index;

2. Nine Hole Peg test;

3. Brunnstrom Fugl Meyer arm-hand test;

4. Nine hole peg test;

5. Erasmus MC modification of Nottingham sensory assessment;

6. Stroke impact scale 3.0;

7. Motor activity log.

Study description

Background summary

Prospective cohort studies show that about 80% of all stroke survivors have an upper limb paresis immediately after stroke. Unfortunately, 60 to 70% of stroke survivors will continue to experience upper extremity functional limitations, which is associated with diminished health related quality of life after stroke. Recent studies have indicated that stroke patients' upper limb function may be improved using specific therapeutic protocols with a strong conceptual motivation. Therefore, powerful randomised clinical trials (RCTs) investigating the effectiveness and testing the conceptual motivation of innovative therapies are urgently needed in stroke rehabilitation. In addition, a better understanding is needed of mechanisms associated with treatment-induced effects in order to improve future treatment strategies. Here, we propose such an RCT that is both clinically and theoretically relevant. The RCT is aimed at investigating the effects of Bilateral Arm Training with Rhythmic Auditory Cueing (BATRAC) and Constrained Induced Movement Therapy (CIMT) in subacute stroke patients with an upper limb deficit. Both interventions will be compared to a Dose-Matched Control Treatment (DMCT) based on usual practice. Apart from an assessment of the intervention-induced changes in upper limb functionality (i.e., primary outcome measure Action Research Arm Test (ARAT)), this BATRAC-CIMT study explicitly aims at uncovering the mechanisms that are associated with regaining dexterity. For this latter purpose, included patients will be stratified with respect to the severity of upper limb paresis (reflecting the intactness of the primary motor system). Moreover, specific predictions regarding intervention-induced

changes will be examined with respect to 1) peripheral stiffness of the upper paretic limb (using a haptic robotic), 2) interlimb interactions governing bimanual coordination (based on kinematics), and 3) cortical activation patterns of ipsi- and contralateral hemisphere as well as cerebellum (using MEG). Thus, besides an evaluation of the relative effectiveness of the treatments of interest, this RCT will shed light on whether exercise-induced improvements in upper limb coordination and dexterity are associated with either ipsi- or contralesional adaptations in the affected and non-affected hemisphere or contralesional cerebellum.

Study objective

1. Both Constrained Induced Movement Therapy (CIMT) and Bilateral Arm Training with Auditory Cueing (BATRAC) are expected to significantly improve upper limb function when compared to a Dose- Matched Control Therapy (DMCT). CIMT is expected to have a larger impact on those subjects who already showed some dexterity at recruitment, given the importance of CST integrity for motor control of the distal part of the upper limb. BATRAC, on the other hand, is expected to be also effective for subjects that were more restricted in this regard, thanks to influences stemming from and reorganizations in the contralesional hemisphere. The effects of BATRAC and CIMT are both expected to sustain over a retention period;

2. Observed therapy-induced changes in upper limb function can be related to changes in (sub)cortical reorganisation, peripheral neuromechanics and sources of interlimb interactions.

Study design

30-03-2009: start inclusion of patients.

28-02-2012: end of inclusion of patients.

Intervention

1. Constrained Induced Movement Therapy (CIMT); 3 times a week 1 hour, for 6 consecutive weeks;

2. Bilateral Arm Training with Auditory Cueing (BATRAC); 3 times a week 1 hour, for 6 consecutive weeks;

3. Dose-Matched Control Therapy (DMCT); 3 times a week 1 hour, for 6 consecutive weeks.

Contacts

Public
L. Delden, van
Van der Boechorststraat 9

Amsterdam 1081BT
The Netherlands
+31 (0)205988495
Scientific
L. Delden, van
Van der Boechorststraat 9
Amsterdam 1081BT
The Netherlands
+31 (0)205988495

Eligibility criteria

Inclusion criteria

1. First-ever ischemic or hemorrhagic stroke in one of the hemispheres within the previous 6 months;

2. Upper limb deficit;

3. 18 to 80 years of age;

4. Motivated to participate;

5. Give written or oral informed consent.

Exclusion criteria

1. Suffer from upper extremity orthopaedic limitations that may affect the results;

2. Not being able to communicate;

3. Disoriented with regard to time and place;

4. Pacemaker or other metallic implants.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-03-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-02-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33953
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1585

Register	ID
NTR-old	NTR1665
CCMO	NL20456.029.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON33953

Study results

Summary results
N/A