ISRCTN82787126 https://doi.org/10.1186/ISRCTN82787126

Technology-supported task-oriented training of arm-hand function in persons with chronic stroke

Submission date 11/04/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/04/2008	**Overall study status** Completed	
Last Edited 01/04/2016	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). One of the most common long-term complications of stroke is weakness or paralysis of one side of the body. It has been found that around 50% of stroke patients are left with limit use of one of their hands/arms, which can make every day activities, such as getting dressed or carrying things, very difficult. Traditionally, stroke patients undergo extensive physiotherapy and occupational therapy in order to try and regain function in their hand/arm. In recent years however, robotics are being used more and more to support this rehabilitation. The Haptic Master robotic system is a commercially available robot which attaches to the patients arm to support training of real-life tasks such as reaching, grabbing and object transportation. The aim of this study is to test the effectiveness of this system in the rehabilitation of stroke survivors with hand/arm weakness.

Who can participate?
Adults who had their first stroke at least one year ago who have hand/arm weakness.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive the task-oriented robot-assisted arm-hand training. The training involves at least two pre-specified skills (such as “eating with a knife and fork” or “using a tray”), with support from the robotic system Haptic Master. The training sessions take place twice a day, four times a week for a period of eight weeks, and involve performing a series of exercises which put together comprise the skill they are learning. Those in the second group receive video instructions to explain the exercises and train on the same schedule but without assistance from the robotic system. Before, halfway through and after the training program, as well as six months later, participants in both groups have their hand/arm function assessed, as well as completing a number of questionnaires about their quality of life.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Medical Center Hoensbroek (Netherlands)

When is the study starting and how long is it expected to run for?
February 2016 to August 2017

Who is funding the study?
Heidelberg University (Germany)

Who is the main contact?
Dr Markus W. Haun
markus.haun@med.uni-heidelberg.de

Contact information

Type(s)
Scientific

Contact name
Mrs Annick Timmermans

Contact details
Zandbergsweg 111
Hoensbroek
Netherlands
6432 CC
+31 45 5282372
A.Timmermans@tue.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
TEchnology-Supported Task-oriented TRaining of Arm-hand function in persons with Chronic Stroke: a multicentre, single-blind, randomised controlled trial

Acronym

TEST-TRACS

Study objectives
An 8-week technology-supported task-oriented training program improves skilled arm-hand performance and quality of life in chronic stroke patients. This improvement is larger after technology supported task-oriented training than after task-oriented training without technology support. Differences in improvement of skilled arm-hand performance between training conditions will last for at least 6 months.

Please note that as of 09/02/09 this record was updated to include an amended anticipated start date. The initial anticipated start date was 01/09/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Medical Ethics Committee of Rehabilitation Foundation Limburg on 7th July 2008 (ref: METC-08-0006; NL23303.022.08)

Study design
Multi-centre single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Stroke/Neurorehabilitation

Interventions
Intervention group:
Participants train on at least two skills they select from a list of 10 skills established in prior research. Participants will receive video-based instruction of predefined task-oriented exercises required for the training. Exercises are offered with increasing difficulty levels for skill components that keep a strong relation with the skill itself. Task-oriented training will be supported by technology, i.e. upper limb kinematics will be recorded during skill performance in stroke patients while training. Feedback about exercise performance (knowledge of

performance and knowledge of results) is given both during and after exercise, based on registration of kinematic parameter information. Patients train for 8 weeks at a minimum of 4 days per week, 30 minutes twice per day.

Control group:
Participants train on at least two skills from a list of 10 skills on offer. Participants will receive video-based instruction of predefined task-oriented training exercises required. Exercises are offered with increasing difficulty levels for skill components that keep a strong relation with the skill itself. Patients train for 8 weeks at a minimum of 4 days per week, 30 minutes twice per day. The control group will perform training without technology support or technology-based feedback on performance.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Arm-hand function:
1. As measured on function level by Brunnstrom-Fugl-Meyer Test
2. As measured on activity level by the Action Research Arm Test and the Motor Activity Log

The outcomes above will be assessed at the following timepoints:
T0: Baseline
T1: After training for 4 weeks
T2: After training for 8 weeks
T3: 6 months after finishing the training programme

Secondary outcome measures
Quality of life at T0, T2 and T3:
1. The 36-item Short Form health survey (SF-36)
2. EuroQol-6D questionnaire

T0: Baseline
T1: After training for 4 weeks
T2: After training for 8 weeks
T3: 6 months after finishing the training programme

Overall study start date
01/03/2009

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. First ever stroke
2. 18 - 85 years old, male and female
3. Clinically diagnosed as having a central paresis of the arm/hand (strength: Medical Research

Council grade 2-3-4 at entry into the study)
4. Post-stroke time greater than or equal to 12 months
5. Fair-good cognitive level (Mini Mental State Examination [MMSE] score greater than or equal to 26 or CogLog score greater than or equal to 26)
6. Ability to read and understand Dutch language
7. Impaired as to at least two of the following skills: drinking from a cup, eating with knife and fork, open/close clothing, taking money from purse, wash/dry body, holding reek/broom/spade, grooming, keyboard work, balancing object while holding it
8. Motivated to train on above mentioned skills

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Neglect: Bells Test, Letter Cancellation Test: minimum omission score of 15% is considered to indicate unilateral spatial neglect
2. Hemianopsia, retrieved from patient's medical file
3. Severe spasticity: Modified Ashworth Scale total arm greater than 4
4. Severe additional neurological, orthopaedic or rheumatoid impairments prior to stroke that may interfere with task performance
5. Broca aphasia, Wernicke aphasia, global aphasia: as determined by the Akense Afasie Test
6. Apraxia: Apraxietest of Van Heugten

Date of first enrolment
01/03/2009

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Medical Center Hoensbroek
Zandbergsweg 111
Hoensbroek
Netherlands
6432 CC

Sponsor information

Organisation
Rehabilitation Foundation Limburg (Stichting Revalidatie Limburg [SRL]) (The Netherlands)

Sponsor details
c/o Dr Henk Seelen
Zandbergsweg 111
Hoensbroek
Netherlands
6432 CC

Sponsor type
Hospital/treatment centre

Website
http://www.srl.nl

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Philips Research (Netherlands)

Funder Name
Technical University Eindhoven (Netherlands)

Funder Name
Rehabilitation Foundation Limburg (Stichting Revalidatie Limburg [SRL]) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/03/2014		Yes	No
Results article	results	13/05/2014		Yes	No