TEchnology-Supported Task-oriented TRaining of Arm-hand function in persons with Chronic Stroke

Published: 16-07-2008
Last updated: 08-05-2024

It is the goal of this study to evaluate the additional value of the Philips Rehabilitation Exerciser for task-oriented training of arm-hand function in chronic stroke patients. Research questions:1) Does an 8 week technology-assisted task-oriented…

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

Summary

ID

NL-OMON31987

Source
ToetsingOnline

Brief title
TEST-TRACS

Condition

- Central nervous system vascular disorders

Synonym
consequences of brain damage due to bleeding, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: The project is funded by Philips Research

Intervention

Keyword: arm-hand skilled performance, stroke, technology, training

Outcome measures

Primary outcome

- Fugl-Meyer test

- Action Research Arm test

- Motor Activity Log

- SF-36

- EuroQoL

Secondary outcome

- kinematics of arm, hand and trunk

- Goal Attainment scaling

- Diary: therapy compliance

Study description

Background summary

Because of improving healthcare, the age of the population increases, leading to an increased incidence of stroke of about 30% in the next 30 years.
About 40% of stroke patients suffer from chronic impairment in arm hand function, affecting their activity and participation level. Functional gains can be made by addressing latent sensorimotor potential, also in the chronic stage after stroke.
It is very much questionable if paramedical staff can accommodate the increase in the need for care. In this light, the development of technology to support training of arm and hand function in stroke patients can be seen as a welcome opportunity.
In SRL, Hoensbroek, training protocols have been developed for task-oriented arm training (TOAT). TOAT offers training of skills by offering functional components that keep a strong relationship with the skill itself. Exercises are offered with increasing difficulty levels. Following skills can be trained:

drinking from a cup , eating with knife and fork, open and close clothing, taking money from purse, wash/dry body, holding reek/broom/spade, grooming, balancing object while holding it, keyboard work.

Study objective

It is the goal of this study to evaluate the additional value of the Philips Rehabilitation Exerciser for task-oriented training of arm-hand function in chronic stroke patients.

Research questions:
1) Does an 8 week technology-assisted task-oriented training program improve arm-hand function/activity and quality of life in persons who are in a chronic phase after stroke?
2) Does an 8 week technology-assisted task-oriented training program improve arm- hand function/activity and quality of life in persons who are in a chronic phase after stroke relative to task oriented training that is not supported by technology?
3) Does the treatment effect of task oriented training lasts longer after technology supported task oriented training relative to task oriented training without technology support in persons who are in a chronic stage after stroke?
4) Is treatment compliance during an 8 week technology-assisted task-oriented training program higher than during an 8 week task-oriented training program without technology support in persons who are in chronic phase after a stroke?

Study design

The TEST-TRACS study is a multi-centre, single-blinded, randomized controlled clinical trial in which an 8 weeks TOAT training, assisted by technology (ULTRA system), is contrasted to TOAT without technology-support from ULTRA.
Average scores and SD scores of the ULTRA kinematic data, the Fugl-Meyer test data and ARA(T) data will be calculated for T0, T1, T2 and T3. Statistical analysis of these data will include repeated measurement AN(C)OVA (multiple comparison), regression analysis, GEE.
The data of MAL, SF-36, EuroQol and other questionnaires will be reported descriptively.

Time schedule:
- training of therapists: Jun 08 - Oct 08
- identification of participants: Oct 08 - Oct 09
- inclusion time: Nov 08 - Oct 09
- data collection: Nov 08 - Apr 10
- data-analysis: Nov 09 - May 10
- reporting: Apr 10 - Jun 10

Intervention

Eighty four persons in chronic stage after stroke will train for 8 weeks, 4 days per week, 2x 30minutes per day on minimum two skills (listed above). Hereby half of them will only be supported by DVD/video-instruction; the other half will be supported by Philips Rehabilitation Exerciser (ULTRA). Following parameters will be registred:
- kinematics of arm and trunk
- Fugl-Meyer Test
- Action Research Arm Test
- Motor Activity Log
- SF-36
- EuroQol
- Goal Attainment Scaling
- Diary Compliance Log

Average scores and SD scores of the ULTRA kinematic data, the Fugl-Meyer test data and ARA(T) data will be calculated for T0, T1, T2 and T3. Statistical analysis of these data will include repeated measurement AN(C)OVA (multiple comparison), regression analysis, GEE.
The data of MAL, SF-36, EuroQol and other questionnaires will be reported descriptively.

Study burden and risks

The risk involved in this study is minimal and does not exceed the risks associated with general daily activities.

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 supratentorial stroke
- 18-85 years old
- clinically diagnosed as having a central paresis of the arm/hand (strength Medical Research Council grade 2-3-4 at entry into the study)
- post-stroke time >=12 months
- fair-good cognitive level: MMSE (score above 26) or CogLog (score above 26)
- ability to read
- ability to understand Dutch language
- persons have to be impaired for 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.
- Motivated to train on above mentioned skills

Exclusion criteria

- severe neglect:
• From medical files persons are selected that perform well on the O-zoek test: difference between omissions right and left >= 2 will not be included. This test is not validated, but is used in SRL and checking on its result will help us contacting persons that are appropriate to be included in this study.
• Letter cancellation test and bell*s test (only part of quantitative evaluation) to ensure that no severe neglect is present. These tests assess neglect in near extrapersonal space. The omission score is calculated. A minimum omission score of 15% is considered to indicate unilateral spatial neglect (USN) in cancellation testing. Ferber and Karnath (2001) found that each of the latter tests only miss 6% of the neglect patients which is acceptable for this study.
- hemianopsia: retrieved from medical patient file

- severe spasticity: Modified Ashworth Scale total arm >4
- severe additional neurological, orthopaedic or rheumatoid impairments prior to stroke that may interfere with task performance
- Broca aphasia, Wernicke aphasia, global aphasia: as determined by Akense Afasie Test (AAT) (information obtained from medical files)
- severe apraxia: apraxietest van Heugten (information from medical files)

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):	01-10-2008
Enrollment:	84
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ISRCTN	ISRCTN82787126
CCMO	NL23303.022.08