Computer based cognitive flexibility training after stroke

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

Summary

ID

NL-OMON40530

Source
ToetsingOnline

Brief title
TAPASS

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: NWO

Intervention

Keyword: computer based, executive functions, stroke, training

Outcome measures

Primary outcome

The primary outcome is executive functioning as measured by several neuropsychological tasks (Fluency, Tower of London, Trail Making Test, letter-number sequencing)

See protocol for a description of these tasks.

Secondary outcome

1) Cognitive flexibility as measured by switchcost (reactietimes op switchtrials compared to reaction times on non -switchtrials) on the switch task.

2) Cognitive functioning as measured by several neuropsychological tasks and computer tasks (see protocol)

3) Training improvement

4) Subjective cognitive functioning and functioning in daily life as measured by: dysexecutive questionnaire (DEX), Cognitive Failure Questionnaire (CFQ), Utrechtse Schaal voor Evaluatie en Revalidatie- Participatie (USER-P), Instrumental activity of daily life scale (IADL), en Short Form Health Survey (SF-36)

5) Imaging analyses (resting state fMRI, Diffusion Tensor Imaging, Voxel Based Morphometry)

Study description

Background summary

Stroke frequently results in executive dysfunctions even in the chronic phase. Executive functions are very important for everyday life activities. Therefore, there is a great need for improved cognitive rehabilitation in stroke patients. One promising way to ameliorate cognitive impairments after stroke is to use computer games as cognitive exercises. A recent review by our group indicates that *brain training* in elderly is beneficial if the training emphasizes cognitive flexibility. Therefore, we hypothesize that it is highly likely that cognitive flexibility training will also result in cognitive improvements in stroke patients. Furthermore, in several studies, changes in brain activity have been observed after intensive cognitive training which relate to improved cognitive functioning. Against this background, we planned the *Training Project Amsterdam Seniors and Stroke* (TAPASS) study.

Study objective

In this study the effectiveness of online cognitive flexibility training on cognitive functioning in stroke patients will be investigated. The aim of this study is to improve executive functions: both trained executive functions as well as untrained executive functions. Moreover, we expect that these functions also improve in everyday life and generalize to other cognitive functions which will improve quality of life. The current study furthermore examines the relationship between changes in cognitive functioning and neuronal alterations. The results of this study can be helpful for development of treatments that assist the recovery of people suffering from stroke.

Study design

This study is a multicenter, double blind, randomized, controlled intervention study with an active and a waiting list control group. The patient (post-acute and chronic) will be randomized over three conditions (cognitive flexibility training, active mock training, and waiting list). The groups will be compared directly before training (T=0), after 6 weeks of training (T=1), directly after (T=2) and 4 weeks after training (T=3). The waiting list control group will be assessed during their waiting list period of 12 weeks, at the same time-points as the training groups. Furthermore, patients will be compared with healthy elderly who had the same training (this latter group is from a different study and will thus not be part of the current protocol).

Intervention

Participants will be randomized over three conditions: online cognitive

flexibility training, online mock training (active control), or waiting list.
The training duration is 12 weeks during which participants will train five times per week for 30 minutes per session. The computer tasks for both conditions have been developed to be visually attractive and motivating. Furthermore, participants will receive direct feedback over their performance during training. The cognitive flexibility training includes tasks that train attention, reasoning, and working memory. The participants will frequently switch between these tasks to assure that cognitive flexibility is needed. The mock training consists of computer tasks that do not train cognitive functioning and will not switch frequently between these tasks to assure that cognitive flexibility is not required. The waiting list group will get access to the cognitive flexibility training after their waiting list period of 12 weeks.

Study burden and risks

All participants will have to train at home during at least 30 minutes per day, five days per week for 12 weeks. Furthermore, participants will be assessed several times. In total, including training, participants will spend approximately 50 hours on this study (54 hours for the waiting list group). We expect that participants will not find the training burdensome because it is designed to be interesting and challenging. Participants who participate in the MRI part of the study will be scanned twice for one hour. To our knowledge there are no risks involved in participating in this study. Difference in benefit is expected between the training and the active control condition. So far none of the treatments has been proven to be superior to the other. Moreover, after the study period, both groups will be offered the opportunity to train with the tasks used in the intervention group.
It is expected that intensive computer based cognitive flexibility training will result in improvement of executive functioning. Patients may benefit from this in their everyday life activities. Furthermore, results of this study can be helpful for development of treatments that assist the recovery of people suffering from stroke.

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

1) Suffered from stroke and referred to rehabilitation; 2) Presence of cognitive dysfunction due to stroke; 3) Age between 30 and 80 years; 4) Daily access to computer with internet connection and able to use mouse; 5) Informed consent for study participation.

Exclusion criteria

1) Any disease other than stroke which results in severe cognitive impairments 2) Severe psychological, psychiatric, or somatic comorbidity which could strongly influence the performance on the neuropsychological assessment and training possibilities 3) Mentally (Telephone Interview Cognitive Status (TICS) score < 26) and physically (medically unstable) not fit enough to complete training protocol. 4) Aphasia, neglect, paresis or paralysis of the preferred hand, colorblindness, invalidating vision or hearing problems, or severe computer fear disabling the participants to fully complete the neuropsychological assessment and training

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-09-2013
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22908
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44685.029.13
OMON	NL-OMON22908