Computer based cognitive flexibility training after stroke

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22908

Source
Nationaal Trial Register

Brief title
Training Project Amsterdam Seniors and Stroke (TAPASS)

Health condition

Stroke patients

Sponsors and support

Primary sponsor: University of Amsterdam
Source(s) of monetary or material Support: National Initiative Brain & Cognition, Netherlands Organization for Scientific Research (NWO).
University of Amsterdam, department of Brain & Cognition

Intervention

Outcome measures

Primary outcome

Executive functioning as measured by neuropsychological tasks (category and letter fluency, Tower of London, D-Kefs TMT number-letter switching, Wechsler Adult Intelligence Scale Letter-Number Sequencing).

The groups will be compared immediately before training and immediately after training.

Secondary outcome

1) Cognitive flexibility as measured by switch-cost (reaction times on switch trials compared to reaction times on non–switch trials) on the switch task.

2) Cognitive functioning as measured by neuropsychological tasks (Trail Making Test condition B corrected for A, Paced Auditory Serial Addition Task, Digit-Symbol-Coding, Rey's auditory verbal learning test, Operation span, N-back, Corsi task, Raven Colored Progressive Matrices, Shipley Institute of Living Scale-2, D-Kefs TMT motor speed condition, Mouse skills tasks, and stop-signal task).

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

Study objective

Main: We expect that cognitive flexibility training will result in a larger improvement in objective executive functioning compared with those who receive mock training or those who are in the waiting list group.
Secondary: It is predicted that cognitive flexibility training will be more effective in stroke patients compared with healthy adults and more effective in the post-acute phase than in the chronic phase post-stroke. Moreover, we expect that cognitive improvement will be related to changes in brain activity. In particular, we expect that resting-state brain activity of stroke patients who receive cognitive flexibility training will converge more to "normal" than of those who did not receive this training.
Explorative: We will explore which lesion characteristics (e.g. type of stroke, size of lesion, brain regions), and other variables (e.g. IQ, age, comorbidities, cognitive flexibility at baseline) predict good outcome.

Study design

The groups will be compared immediately before training, after 6 weeks of training, immediately after, and 4 weeks after training.

Intervention

Online cognitive flexibility training, online mock training (active control), or waiting list. The training duration is 12 weeks, five times per week for 30 minutes per session.
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 tasks that do not train cognitive functioning and no frequent switches between tasks.

Uva.braingymmer.com is used for both training groups.

Contacts

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Eligibility criteria

Inclusion criteria

Key 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

Key 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 (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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	22-05-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40530
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5028
NTR-old	NTR5174
CCMO	NL44685.029.13
OMON	NL-OMON40530

Study results