Karman Line: Strategy-game supported treatment for slowed information processing speed (IPS)

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The experimental treatment (game-supported TPM training) will contribute to a more effective generalisation of compensatory strategies to untrained tasks as compared to the active control group (CogniPlus training).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON22586

Source
NTR

Brief title
KARMAN_TPM

Condition

- Structural brain disorders

Health condition

Acquired brain injury (ABI)

Research involving
Human

Sponsors and support

Primary sponsor: Operationeel Programma Oost (OP Oost)

Secondary sponsors:	Klimmendaal revalidatiespecialisten
Source(s) of monetary or material Support:	European Regional Development Fund (ERDF)/Operationeel Programma Oost (OP Oost)

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

The primary outcome measure is an objective assessment of strategy-use in an untrained experimental task (Online Meeting Task) measures before (T0) and post-treatment (T1).

Secondary outcome

The secondary outcome is a standardised measuring scale to evaluate to what extent three individual treatment goals are achieved (Goal Attainment Scale) before (T0) and post-treatment (T1). Moreover, a neuropsychological test battery and questionnaires will be administered to assess information processing speed and other aspects of cognitive functioning at baseline (T0). Questionnaires and part of the neuropsychological tests will be repeated post-treatment (T1) to control for potential nonspecific recovery. A follow-up measurement (T2) is obtained that includes several questionnaires three months after treatment.

Study description

Background summary

Rationale: Brain-injured patients referred for outpatient rehabilitation experience difficulties with processing and retaining information due to slowed information processing speed (IPS), or mental slowness. Patients may experience externally observed slowness, such as slow performance on neuropsychological tasks, as well as problems with information processing in daily life in which events proceed at a rate they cannot control. Time Pressure Management (TPM) training is a successful treatment for these problems. The treatment allows patients to determine during which moments of a situation they experience time pressure and learn strategies to compensate for their slowed speed of information processing. However, there is only a limited amount of time during each session to learn and train these strategies with the cognitive trainer. Our research tries to fill this gap by introducing treatment-supporting strategy games that support the learning process of the patient, give more insight into their

progression and allow the patient to practice the strategies at home in a safe and controlled environment. Until now brain games have only focused on function training rather than learning compensatory strategies, with no or limited generalization of improvement for a patients daily life. Our hypothesis is that the game-supported Time Pressure Management (TPM) training will contribute to more effective generalisation of compensatory strategies to untrained tasks and thereby contributing to the improvement of strategy-use for slowed information processing speed (IPS) in daily life. Objective: The primary objective is to examine the efficacy of a strategy-game supported TPM intervention for the treatment of slowed IPS of patients with acquired brain injury (ABI) in the chronic phase (>6months post-onset) focusing on a generalisation of strategy-use in an untrained experimental task. Our secondary objective is examining the subjective experience of participating patients as measured by GAS (Goal Attainment Scale). Study design: The study will be a randomised controlled trial in which the efficacy of the game-supported TPM training (8 weeks) will be compared with an active control group (8-week CogniPlus training). Study population: The study population consists of patients referred for outpatient cognitive rehabilitation. Participants eligible for the study must experience problems with slowed IPS due to acquired brain injury (ABI) of nonprogressive nature (i.e. TBI, stroke) with a minimal time post-onset of 6 months. Age has to be between 18 and 70 and participants have to live independently at home. Slowed IPS will be assessed by the Mental Slowness Questionnaire (MSQ). Participants will be recruited from the outpatient clinic and the department of neurorehabilitation of Klimmendaal rehabilitation centre. In the course of 3 years 60 participants will be recruited. Intervention: The investigational treatment is based on the standard TPM training (see Introduction and Rationale), part of the cognitive rehabilitation intervention at Klimmendaal rehabilitation centre is used for ABI patients with slowed IPS. The investigational treatment will combine the TPM training with a cognitive strategy game targeting slowed IPS. Both the training as well as the game aim to teach cognitive strategies for situations in which the patient experiences time pressure and thereby give possibilities for the patient to alleviate problems related to slowed IPS. The training is given by the therapist and the game will be played at home. The active control group will follow the CogniPlus training in guidance of the therapist at the rehabilitation centre. This training is aimed to improve the speed of information processing and does not teach the patient strategies for dealing with slowed information processing in daily life. Both types of intervention consist of 8 sessions (max 60 minutes) and will be given once a week. Main study parameters/endpoints: The main study parameter is strategy-use measured by an experimental task that investigates the application of cognitive strategies in an online meeting (int. al. the percentage change of the number of correct strategies). Participants perform the task before and after treatment (two counterbalanced parallel versions). A secondary parameter of the study is Goal Attainment Scaling (GAS). Moreover, questionnaires and neuropsychological tests will be administered. All measurements will be administered at baseline and post-treatment. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All tests and methods that are used are non-invasive and not stressful for the patient. All tests and tasks will be widely-used validated and reliable paper-pencil or computerized tasks. The participant can work at his/her work pace, and if desired additional breaks will be taken. Treatment is also non-invasive and scarcely stressful: a therapist will measure such as inserting a resting break during training. The treatment-supporting game will be played at home for one hour per week. Again, the participant can work at his/her own pace, take breaks during and between the levels and can stop playing the game at any moment (e.g. if

the participant gets tired).

Study objective

The experimental treatment (game-supported TPM training) will contribute to a more effective generalisation of compensatory strategies to untrained tasks as compared to the active control group (CogniPlus training).

Study design

T0 (baseline), T1 (post-treatment), T2 (3-month follow-up)

Intervention

game-supported cognitive training

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

Age: 18-70,

Non-progressive acquired brain injury,

Minimal time post-onset of 3 months,

Outpatient rehabilitation,

Living independently at home,

Slowed information processing speed (as indicated by MSQ score higher than 13)

Exclusion criteria

Inability to speak/understand the Dutch language,

Severe psychiatric problems (history),

Neurogenerative disorders,

Substance abuse,

Severe cognitive comorbidity,

Unable to look at a computer screen and/or operating a keyboard and/or operating a computer mouse,

Aphasia,

Neglect

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-11-2021
Enrollment:	36
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
"1. Will individual participant data be available (including data dictionaries)? Yes, 2. What data in particular will be shared? Individual-level deidentified patient data (all data collected during the trial), 3. What other documents will be available? Study Protocol, Informed Consent Form, Survey results, Statistical code, Spreadsheets, 4. When will data be available (start and end dates)? Immediately following publication. No end date, 5. With whom? Researchers who provide the authors of the article a detailed protocol for the proposed study, and to supply information about the funding and resources you have to carry out the study, 6. For what types of analyses? To achieve aims in the approved proposal, 7. By what mechanism will data be made available? Proposals should be directed to amy.abelmann@donders.ru.nl or dirk.bertens@donders.ru.nl. To gain access, data requestors will need to sign a data use agreement. Data are available at the data management infrastructure (Donders Repository) of the Donders Institute for Brain, Cognition and Behaviour (https://data.donders.ru.nl/)."

Ethics review

Approved WMO

Date:	06-01-2021
Application type:	First submission
Review commission:	METC Oost-Nederland p/a Radboudumc, huispost 628, Postbus 9101 6500 HB Nijmegen 024 361 3154 commissiemensgebondenonderzoek@radboudumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 51933
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9437
CCMO	NL74818.091.20
OMON	NL-OMON51933

Study results