A strategy game supporting goal management training intervention for the treatment of executive problems after acquired brain injury: A randomized controlled pilot study for usability and preliminary efficacy

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52362

Source
ToetsingOnline

Brief title
Pilot GMT Karman Line

Condition

- Other condition
- Structural brain disorders

Synonym
Acquired brain injury, brain damage

Health condition

Niet-aangeboren hersenletsel

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Groot Klimmendaal
Source(s) of monetary or material Support: Operationeel Programma Oost (OP Oost)

Intervention

Keyword: Acquired brain injury, Executive disorder, Strategy games, Transfer effects

Outcome measures

Primary outcome

The main study parameters are to explore the usability and playability of the

strategy game, and to assess the feasibility of the

shortened GMT treatment. Participants have to complete the system usability

scale (SUS) questionnaire at the end of treatment.

Furthermore, interviews with participants will be carried out to validate the

findings from the survey and to gather participants*

experience of using the game, the playability and factors that may affect their

treatment outcome. In addition, a questionnaire survey

to investigate therapists* acceptance and intention to use the treatment for

acquired brain injury cognitive rehabilitation will be

conducted in order to assess the feasibility.

Secondary outcome

Secondary study parameters are a standardized scale measuring performance of

four different untrained IADL tasks (two tasks at

baseline, two other tasks post-treatment). Also, the achievement of goals set

(GAS), participation (USER-P), insight and reported

severity of executive problems (BRIEF-A), a neuropsychological assessment

regarding executive functioning, and the subjective

experience of strategy use in daily life and during the performance of IADL

tasks.

Study description

Background summary

These difficulties can be characterized as executive deficits, which can vary from relatively mild to rather severe. Executive deficits lead to real-life everyday disorganization and difficulties in instrumental activities of daily living (IADL tasks). Goal Management Training (GMT) is a successful treatment for executive deficits and helps to structure activities in daily life. GMT entails learning and applying an algorithm, in which a daily task is subdivided into multiple steps to handle executive difficulties of planning, and problem solving. Patients are taught compensatory strategies not to strengthen the executive functions, but to enable them to minimize disabilities and participation problems and to function more independently in daily life. The currently implemented GMT treatment in the Netherlands is aimed at relearning two specific tasks. However, to adopt the GMT strategy and ensure maximal profitability for patients, they have to learn to use the algorithm in different situations and tasks, which requires a comprehensive, time-consuming and thus labour-intensive treatment. Along with this, brain games become increasingly attractive as an (add-on) intervention, most notably in an effort to develop home-based personalized care, and because of their machine learning algorithms which tailors the game to the level of the individual player. Until now, however, the rationale behind brain games is based on what can be considered the restorative approach (i.e. strengthening of executive problems) rather than practicing compensatory strategies, with no transfer to improvements in daily life functioning. The present study fills a gap in the literature by investigating a new developed treatment

that incorporates GMT and a treatment supporting strategy game in a pilot sample of brain injured patients.

Study objective

The primary objective of this pilot study is to investigate the feasibility of GMT with a new game that incorporates strategy training in improving executive functions in a pilot sample of brain-injured patients. This study investigates the usability and acceptability of our new developed GMT treatment to brain-injured patients in the chronic phase (>3 months post-onset), and obtains an efficacy estimate, focusing on transfer of treatment effects to untrained (instrumental) activities of daily living.

Study design

Brain-injured patients will be randomized into the strategy game supported GMT treatment and an information group. Both treatments consist of a 7-week training comprising 7 one-hour sessions.

Intervention

The investigational treatment is based on the standard GMT treatment, part of the cognitive rehabilitation intervention at Klimmendaal that is used for ABI patients with executive problems. The investigational treatment will include a shortened version of GMT in combination with a compensatory strategy game which allows the patient to learn and apply the algorithm of GMT in a safe and controlled environment. This means that the multiple steps of the GMT will be learned during the treatment sessions under guidance of a therapist as well as in their own home environment by using the compensatory strategy game. In the information group, education and information is provided about various non-specific consequences of acquired brain injury. Both the investigational GMT treatment and information group will last 7 weeks.

Study burden and risks

The burden in the study consists of participating in two repeated measurements, therapy sessions, and homework assignments. All brain-injured patients who receive a treatment program at the Klimmendaal Rehabilitation Center start with the information group. For this reason, we decided to include the information group as our active control condition to reduce the burden of patients in obtaining our secondary study objective. 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 in his/her own pace, and if desired additional breaks will be taken. Treatment is non-invasive and scarcely stressful: a therapist will always be present and assess the patient*s burden and eventually take appropriate measures such as inserting a resting break. Participants assigned to both the GMT group and the information group will have seven 1-hour sessions.

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

Age: 18-70
Non-progressive acquired brain injury

Minimal time post-onset of 3 months
Outpatient rehabilitation
Living independently at home
Executive problems evidenced by a clinically meaningful (increased) score on the BRIEF-A

Exclusion criteria

Inability to speak/understand the Dutch language
Severe psychiatric problems (history)
Neurodegenerative disorders
Substance abuse
Severe cognitive comorbidity (i.e. dementia)
Aphasia
Neglect
No access to a smartphone, and laptop or tablet
Unable to look at a computer screen for 15 minutes a day
Unable to operate a keyboard and/or computer mouse

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-05-2022
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 26575
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL74855.091.20
OMON	NL-OMON26575