Evaluation of a Compensatory Brain Game supporting Goal Management Training intervention targeting executive function after Acquired Brain Injury using single-case experimental design methodology

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

Summary

ID

NL-OMON51318

Source
ToetsingOnline

Brief title
SCED GMT Brain Game

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, Compensatory brain games, Executive disorder, Single-case experimental design

Outcome measures

Primary outcome

The main study parameter is the OxMET-NL, a computer-tablet based version of the Multiple Errands Test. The task requires patients to buy six items and to answer two questions. Participants are allowed to complete the tasks in any order. Participants perform different parallel versions of the OxMET-NL twice a week during the baseline and intervention phase (see study design for more details).

Secondary outcome

The secondary study parameters are the performance on two trained IADL tasks, goal achievement (GAS), and subjective strategy use (VAS).

Study description

Background summary

The main cognitive complaint in brain-injured patients is often the everyday

disorganization caused by executive function (EF) deficits. In order to minimize the everyday disorganization, effective EF interventions are required. Interventions which incorporate compensatory strategies have the potential to enable patients to minimize disabilities, minimize participation problems and to function more independently in daily life. A well-known evidence-based intervention that incorporates compensatory strategies is Goal Management Training (GMT). 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. To adopt the GMT strategy and ensure maximal profitability for patients, they have to learn to use the algorithm in different situations and tasks. Therefore, GMT is 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. 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 little or no transfer to improvements in daily life functioning. This study therefore aims to assess the potential of a newly developed Brain Game, based on compensatory strategies, as an add-on to GMT to develop a shortened and partly home-based GMT intervention.

Study objective

The primary objective of this study is to assess whether the use of a compensatory brain game supported GMT treatment could be of interest in people with EF deficits after ABI, to improve goal achievement, their executive function performance during goal-related tasks, and their executive performance during an ecological valid shopping task.

Study design

The study will be a multiple-baseline across individuals single-case experimental design (SCED).

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 GMT in combination with a compensatory brain 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 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. The investigational GMT treatment will consist of 6 treatment sessions given twice a week (with a total duration of 3

weeks).

Study burden and risks

The burden in the study consists of participating in repeated measurements, therapy sessions, and homework assignments. All tests and methods that are used are non-invasive and not stressful for the patient. All tests and tasks will be based on widely-used validated and reliable paper-pencil or computer tasks. Treatment is non-invasive and scarcely stressful: a therapist will always be present and assess the patients burden and eventually take appropriate measures such as inserting a resting break.

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: 18-75 jaar
Non-progressive acquired brain injury
Minimal time post-injury 3 months
Outpatient rehabilitation
Living independently at home
Executive disorder evidenced by a neuropsychological assessment

Exclusion criteria

Inability to speak/ understand the Dutch language
Severe psychiatric problems (history)
Neurodegenerative disorders
Substnace abuse
Several 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
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-04-2023
Enrollment:	4

Type:	Actual

Ethics review

Approved WMO Date:	31-08-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-06-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL81342.091.22