

# Strategy game supporting goal management training intervention

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26575

### Source

Nationaal Trial Register

### Brief title

KarmanGMT

### Health condition

Acquired brain injury

## Sponsors and support

**Primary sponsor:** The European Regional Development Fund (ERDF)

**Source(s) of monetary or material Support:** The European Regional Development Fund (ERDF)

## Intervention

## Outcome measures

### Primary outcome

The main study parameter is a standardized scale measuring performance of an untrained IADL task (int. al. the percent change in the number of correct steps) before (baseline) and

after treatment (post treatment). The untrained IADL tasks will be divided into multiple steps using the GMT method. These steps will be assessed using three categories: 1) competent; 2) questionable/ineffective; 3) deficit, using task-specific assessment forms.

In order to assess the secondary objective of the study, patients also perform an untrained IADL task at 3 months follow-up. The order of the untrained tasks will be counterbalanced across patients.

## **Secondary outcome**

Secondary study parameters of the study are the performance on two trained IADL tasks and the subjective experience of strategy use. Moreover, questionnaires and neuropsychological tests will be administered. All measurements will be administered at baseline, post-treatment and at 3 months follow-up.

# **Study description**

## **Background summary**

Executive function impairments are one of the most persistent and disruptive consequences of acquired brain injury (ABI), causing significant disabilities in maintaining efficient and independent functioning in daily-life, especially in novel, complex or demanding situations. Goal management training (GMT) is a successful treatment for these impairments and helps maintaining intentions in goal-directed behaviour to structure activities in daily life. GMT entails learning and applying a strategy, in which a daily task is subdivided into multiple steps to handle executive function problems in planning, and goal-directed behaviour. 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. To adopt the GMT strategy and ensure maximal profitability for patients, they have to learn to use the strategy in different situations and tasks, which requires a comprehensive, time-consuming and thus labour-intensive treatment. Along with this, serious 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 serious games is based on what can be considered the restorative approach (i.e. strengthening of executive problems) rather than practicing compensatory strategies, with no or little transfer to real-life situations. The present study fills a gap in the literature by combining GMT with a treatment supporting compensatory strategy game, and focusing on transfer of treatment effects to everyday functioning. If the strategy game supported GMT treatment proves to be effective, this may contribute to a shortened evidence based treatment for executive problems.

## **Study objective**

We expect that the experimental treatment (shortened GMT along with a cognitive strategy game) and control treatment (standard GMT) are equal in effect.

## **Study design**

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

## **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 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 standard GMT patients will learn to use the algorithm and the performance of IADL tasks during the treatment sessions and with paper and pencil tasks. The investigational GMT treatment will consist of 7 sessions (max. 60 minutes), whereas the standard GMT treatment consists of 9 sessions. Both types of GMT will be given once a week.

## **Contacts**

### **Public**

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## **Eligibility criteria**

### **Inclusion criteria**

Patients will be eligible if they have sustained any type of acquired brain injury of non-progressive nature in the past, being more than three months post injury and if their executive function score on the BRIEF-A is clinically meaningful. Other inclusion criteria are:

(1) aged between 18 and 70 years; (2) referred for outpatient rehabilitation and (3) living independently at home.

## Exclusion criteria

Exclusion criteria are: (1) inability to speak/ understand the Dutch language; (2) co-morbidity that might affect outcome (e.g. neurodegenerative disorders, aphasia, neglect, and major psychiatric illness); (3) substance abuse; (4) no access to a smartphone, laptop or tablet; (5) unable to look at a computer screen for 15 minutes; and (6) being unable to operate a keyboard or computer mouse.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-02-2021
Enrollment:	64
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	14-01-2021

Application type:

First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 52362

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL9200
CCMO	NL74855.091.20
OMON	NL-OMON52362

## Study results