

# Strategy game supporting goal management training intervention

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

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON26575

### Bron

Nationaal Trial Register

### Verkorte titel

KarmanGMT

### Aandoening

Acquired brain injury

## Ondersteuning

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

**Overige ondersteuning:** The European Regional Development Fund (ERDF)

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

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.

### **Doel van het onderzoek**

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

### **Onderzoeksopzet**

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

## Onderzoeksproduct en/of interventie

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.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Actieve controle groep

### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-02-2021
Aantal proefpersonen:	64
Type:	Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies	
Datum:	14-01-2021
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52362

Bron: ToetsingOnline

Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten