

# Evaluation of the Karman Line memory strategy training, a combined computerized and face-to-face compensatory treatment targeting memory complaints after acquired brain injury, using single-case experimental design methodology.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON56938

### Source

ToetsingOnline

### Brief title

SCED KL Memory strategy training

### Condition

- Other condition
- Structural brain disorders

### Synonym

1 - Evaluation of the Karman Line memory strategy training, a combined computerized ... 6-05-2025

acquired brain injury, brain damage

## **Health condition**

Niet-aangeboren hersenletsel

## **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Klimmendaal Revalidatiespecialisten

**Source(s) of monetary or material Support:** Onderzoek wordt uitgevoerd als onderdeel van opleiding tot klinisch neuropsycholoog

## **Intervention**

**Keyword:** Acquired Brain Injury, Compensatory brain games, Memory Disorder, Single-case experimental design

## **Outcome measures**

### **Primary outcome**

The main study parameter are the three most common memory complaints selected from the 13-item scale of the everyday memory questionnaire-revised (EMQ-R).

### **Secondary outcome**

Secondary study parameters include the impact of memory problems on activities and participation, the achievement of personalized treatment goals, objective strategy use, objective memory functioning, metacognitions about memory and measures of feasibility by patients and practitioners.

## **Study description**

### **Background summary**

Acquired brain injury (ABI) often results in memory deficits that can have a great impact on social or vocational functioning of patients. Treatment of memory dysfunction consists of optimizing memory performance by using

effective compensation strategies. Several effective memory-strategy programs have been developed. These often contain labor-intensive treatment-protocols. For this reason, we developed a blended care training of memory strategies, which consists of a shortened traditional face-to face treatment in combination with an innovative Brain Game based on compensation strategies. This is a promising cost-effective intervention that provides the possibility of repeated practice at home in a safe and imaginative digital environment. Until now, brain games on restore brain function, of which effects do not generalize to daily life functioning. Our hypothesis is the compensation brain game will promote generalization, also after rehabilitation ends.

## **Study objective**

The primary objective is the evaluation of the potential positive effect of a compensatory memory strategy game on effective coping with memory problems and reducing subjective memory failures in ABI patients with memory deficits in the chronic phase of acquired brain injury (>3 months after injury).

## **Study design**

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

## **Intervention**

The memory strategy training consists of six weekly treatment sessions under guidance of a therapist. The protocol is a shortened version of an existing memory strategy training. In the sessions, patients get information about memory and memory strategies and learn to apply those to their personal treatment goals. In between the sessions, the participant will work on personal memory goals and practice the strategies by playing the corresponding memory game at home.

## **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

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- memory deficits (evidenced by a neuropsychological assessment)
- memory complaints (evidenced by a questionnaire)
- Age: 18-75 years
- Non-progressive acquired brain injury
- Minimal time post-onset of 3 months
- Outpatient rehabilitation
- Living independently at home
- Premorbid functioning: primary+secondary school (score 4 on the Verhage scale)

### Exclusion criteria

- Inability to speak and/or understand the Dutch language
- Severe disorders in executive functioning
- Severe psychiatric problems
- Neurodegenerative disorders
- Substance abuse
- Aphasia
- Neglect
- No access to a smartphone and a tablet/laptop with internet connection
- Unable to look at a computer screen for 15 minutes a day
- Unable to operate a keyboard 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):	21-01-2025
Enrollment:	8
Type:	Actual

## Ethics review

Approved WMO	
Date:	06-08-2024
Application type:	First submission
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	NL86020.091.24