# Wayfinder: Assessing the effectiveness of a navigation rehabilitation training

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27459

**Source**
NTR

**Brief title**
Wayfinder-NRT

**Health condition**

spatial navigation impairments, acquired brain injury, cognitive rehabilitation, serious gaming

### Sponsors and support

**Primary sponsor:** Leiden University
**Source(s) of monetary or material Support:** STW: Takeoff

### Intervention

### Outcome measures

**Primary outcome**

Overall self-reported navigation impairments, measured using the Wayfinding Questionnaire.

**Secondary outcome**

Objective navigation performance, measured using the Virtual Tübingen Test.

Self-reported navigation impairments on the three subscales of the Wayfinding Questionnaire.

Other study parameters include: questionnaires (Computer use self-efficacy, Utrecht scale for evaluation of rehabilitation participation), goal attainment scaling and cognitive performance on standardized neuropsychological tests (Corsi block tapping task, Digit Span, shortened Raven advanced progressive matrices, Dutch adult reading test, Trail making test, line bisection test).

# Study description

### Background summary

Spatial navigation is a complex cognitive ability that is essential to our daily functioning. Twenty-nine percent of mild stroke patients report navigation problems. Recent literature shows that navigation impairments are not limited to stroke patients, but can occur as a result of many types of brain injuries. Despite the severity and prevalence of navigation impairments no standardized rehabilitation treatment is currently available. We have developed a novel navigation rehabilitation training aimed at tackling the multifaceted nature of navigation impairments. Performance on subcomponents of navigation is assessed to identify the nature of an individual's navigation impairments. Using combination of psycho-education and virtual reality eHealth software, patients are trained to develop compensatory navigation strategies. In this study we will investigate the effectiveness of the NRT.

Amendement:
Until 6-3-2019 inclusion criteria 1 was: "Impaired score on any subscale of the Wayfinding Questionnare". An amendement was submitted to and accepted by the CME Leiden, allowing for inclusion on the basis of self-reported navigation complains, whether or not this was reflected in the Wayfinding Questionnare.

### Study objective

Acquired brain injury patients often report navigation impairments. A cognitive rehabilitation therapy has been developed in the form of a serious game. The aim of this study is to investigate the effectiveness of this navigation rehabilitation training (NRT). It is hypothesized that navigation impairment complaints of patients will be reduced after engaging in navigation rehabilitation training. Furthermore, we expect that the objective navigation performance will increase as a result of training with the application.

### Study design

Data will be collected at five measuring points (screening, T0, T1, T2 and T3). Respondents will perform the eligibility assessment at home by filling out an online screening questionnaire and participating in a telephone interview. All eligible participants will be invited to the Leids Universitair Behandel Expertise Centrum (LUBEC) of the Faculty of Social Sciences of the Leiden University (FSW) to perform a baseline measurement (T0). Following the baseline measurements, participants are assigned to the experiment or control group (T1). Participants in the control group will receive treatment as usual. Participants in the experimental group will engage in the NRT. The NRT consists of a psycho-education session and an eHealth training program. The psycho- education is a single session with a navigation expert. The eHealth training program will consist of 12 home-training sessions using the Wayfinder software. One week following the intervention period, all participants will be re-invited to the FSW to perform the post-treatment measurement (T2). Three weeks later, all participants will be asked to fill in an online follow-up questionnaire (T3) followed by a debriefing about the purpose of the study.

**Intervention**

The NRT intervention consists of a psycho-education session and individual training sessions using the Wayfinder software, a serious-gaming eHealth application that is installed on and used from a patient's home computer. The Wayfinder software is designed to train patients in the use of compensatory navigation strategies using game-like assignments in virtual environments. Participants will engage in a single psycho-education session (30 minutes) and engage in 12 individual home-training sessions using the Wayfinder software over a period of 6 weeks (30 minutes per session, 2 sessions per week).

# Contacts

**Public**
Pieter de la Court Building

M.N.A. van der Kuil
Wassenaarseweg 52

Leiden 2333 AK
The Netherlands
+31 (0)71 527 3831
**Scientific**
Pieter de la Court Building

M.N.A. van der Kuil
Wassenaarseweg 52

Leiden 2333 AK
The Netherlands

+31 (0)71 527 3831

# Eligibility criteria

## Inclusion criteria

1. Self-reported navigation impairments

2. Clinically diagnosed acquired brain injury, first or recurrent
(Traumatic brain injury patients must have been hospitalized to the intensive care unit following the injury)

3. Non-acute phase of the brain injury (> 6 months post event)

4. PC of Mac computer at home with internet access

5. 18-85 years of age

6. Sufficient comprehension and communication (Dutch)

## Exclusion criteria

1. Physically and/or mentally unable to participate

2. Known spatial neglect, diagnosed clinically with neuropsychological neglect test (Line Bisection test or cancellation task)

3. Unable to control computer mouse and keyboard

4. Interfering psychiatric disorder (dementia, depression, anxiety disorder, schizophrenia, autism, obsessive-compulsive disorder, personality disorder etc.) or substance abuse.

5. Non-Dutch speaking

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |

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| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 11-06-2018 |
| Enrollment: | 64 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

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|---|---|
| Date: | 20-06-2018 |
| Application type: | First submission |

## Study registrations

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

ID: 46611
Bron: ToetsingOnline
Titel:

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL7097 |
| NTR-old | NTR7295 |

| Register | ID |
| --- | --- |
| CCMO | NL62050.058.17 |
| OMON | NL-OMON46611 |

# Study results

**Summary results**

n.a.