

Wayfinder: Assessing the effectiveness of a navigation rehabilitation training

Published: 28-05-2018

Last updated: 15-05-2024

The primary objective of this study is to determine whether self-reported spatial navigation impairment complaints in acquired brain injury patients are reduced as a result of engaging in a behavioural navigation rehabilitation training. The...

| | |
|------------------------------|--|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Cognitive and attention disorders and disturbances |
| Study type | Interventional |

Summary

ID

NL-OMON46611

Source

ToetsingOnline

Brief title

Wayfinder-NRT

Condition

- Cognitive and attention disorders and disturbances

Synonym

navigation impairment, topographical disorientation

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Leiden

Source(s) of monetary or material Support: STW: Takeoff

Intervention

Keyword: compensation, eHealth, navigation, rehabilitation

Outcome measures

Primary outcome

A decrease in self-reported navigation complaints, measured with the Wayfinding questionnaire

Secondary outcome

An increase in objective navigation performance, measured with the Virtual Tübingen 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 navigation rehabilitation training. It is hypothesized that navigation impairment complaints of patients will be reduced after engaging in the training.

Study objective

The primary objective of this study is to determine whether self-reported spatial navigation impairment complaints in acquired brain injury patients are reduced as a result of engaging in a behavioural navigation rehabilitation training. The secondary objective is to determine whether objective navigation

performance improves as a result of the training.

Study design

Single-blind randomized control trial employing a control and experimental group.

Intervention

The navigation rehabilitation training consists of a psycho-education session and individual training sessions using the Wayfinder software, a serious-gaming eHealth application which 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 receive a single psycho-education session at the university (30 minutes) and engage in 12 individual training sessions using the Wayfinder software over a period of 6 weeks. (30 minutes per session, 2 sessions per week).

Study burden and risks

A potential risk of participation is the experience of simulation sickness during exposure to Wayfinder software. Simulation sickness is a side effect of interaction with virtual environments. Symptoms of simulation sickness include in dizziness, headaches and nausea. The symptoms are minor, short-lived and can be easily controlled by stepping away from the computer. We consider the risks of simulation sickness to be negligible as no instances of simulation sickness have been reported in a prior feasibility study with 43 healthy participants and a usability study with 27 acquired brain injury patients. Patients engage in the training program for six consecutive weeks, in which patients use the application for one hour per week. To reduce the burden, game components are included in the training such as achievements and motivational rewards.

The potential benefits of participation are considerable. Aside from the potential positive effects which might result from the navigation rehabilitation training intervention in this study, participants will receive psycho-education on spatial cognition and navigation. Psycho-education will help participants to identify the nature of their impairments and give insight into their disabilities.

Contacts

Public

Universiteit Leiden

Wassenaarseweg 52
Leiden 2333 AK
NL
Scientific
Universiteit Leiden

Wassenaarseweg 52
Leiden 2333 AK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Report navigation impairments after acquired brain injury.;Clinically diagnosed acquired brain injury.;Non-acute phase of the brain injury (> 6 months post event).;PC or Mac computer at home with internet access.;18-85 years of age.;Sufficient motivation to use the intervention for 6 weeks.;Sufficient comprehension and communication to partake in the intervention.;Written informed consent.

Exclusion criteria

Physically and/or mentally unable to participate;Known spatial neglect, diagnosed clinically with neuropsychological neglect test (Line Bisection test or cancellation task);Interfering psychiatric disorder (dementia, depression, anxiety disorder, schizophrenia, autism, obsessive compulsive disorder, personality disorder etc.) or substance abuse.;Non-Dutch speaking

Study design

Design

| | |
|---------------------|-------------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |

Primary purpose: Treatment

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 11-06-2018 |
| Enrollment: | 64 |
| Type: | Actual |

Ethics review

| | |
|--------------------|-------------------------------------|
| Approved WMO | |
| Date: | 28-05-2018 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

| | |
|--------------------|-------------------------------------|
| Approved WMO | |
| Date: | 06-03-2019 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27459

Source: NTR

Title:

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL62050.058.17 |
| OMON | NL-OMON27459 |