The use of Virtual Reality for Cognitive Rehabilitation Following Acquired Brain Injury

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Primary objective: Inpatient Group: The primary objective of the research with the inpatient group is to assess whether there is a treatment effect in cognition (at T2) compared to baseline (T1) using conventional rehabilitation, as compared to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52174

Source
ToetsingOnline

Brief title
VRCRABI

Condition

- Other condition

Synonym
Brain injury; brain damage

Health condition

Brain infarct or haemorrhage; Transient Ischaemic Attack; Traumatic Brain Injury; Cerebral tumors (resection)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Industry,NeuroReality B.V.

Intervention

Keyword: acquired brain injury, cognitive rehabilitation, virtual reality

Outcome measures

Primary outcome

Inpatients - Composite score of the neuropsychological tests (NPO)

The primary measure of interest in this study is cognitive performance. This will be operationalised through the creation of a neuropsychological composite score from a battery of cognitive tests. We are interested in examining whether a course of cognitive rehabilitation can induce/create treatment effects of cognitive performance. We will compare the neuropsychological composite score before (T1) and after the training procedure (T2).

To achieve this aim, the experimental group will undergo conventional rehabilitation with the addition of VR. To ensure that any observed differences are not due to spontaneous recovery or test-retest effects, we will compare changes in cognitive performance (T1 - T2) to an active control group who will take part in conventional rehabilitation only. We are also interested in understanding whether any observed improvements are robust and maintained over a 6-week period (T3). Therefore, we will also investigate whether cognitive performance changes from the post training time point (T2) to the follow up timepoint (T3).

Outpatients - CoCo-P Questionnaire

Another primary consideration of the current study is to understand whether any cognitive improvement observed in the neuropsychological tests and functional questionnaires also transfers to a treatment effect in cognition, quality of life, and activities of daily life. In order to operationalize this construct, we have chosen the CoCo-P Questionnaire.

Performance on the CoCo-P Questionnaire will be examined pre (T1) and post (T2) the training protocol, and once again at the 6- week follow up sessions (T3) to enable us to understand both immediate and more delayed treatment effects, e.g., to observe if improvements are robust and maintained over a 6-week period (T3). To achieve this aim, the experimental group will undergo conventional rehabilitation with the addition of VR. Once again, to ensure any effects are not simply due to spontaneous recovery or test-retest effects, changes in performance will be compared to a control group undergoing conventional rehabilitation only.

Secondary outcome

1. The difference between inpatient versus outpatient performance in terms of treatment effect.
2. Interaction effects of NPO, questionnaires, medical and demographic factors.

Study description

Background summary

The reported prevalence of cognitive disorders after acquired brain injury (ABI) in at least one or multiple domains ranges from 10-93% (van der Naalt et al., 1999; van Kessel et al., 2017; Nys et al., 2005; Nys et al., 2007; de Haan, Nys & van Zandvoort, 2006; Tatemichi et al., 1994, Rasquin et al., 2004). Cognitive disorders have a negative influence on both performance on *activity* and *participation* level (van der Kemp et al., 2017; van Velzen et al., 2009; Nys et al., 2005).

Research has demonstrated the importance of rehabilitation following ABI. However, despite benefits, conventional ABI rehabilitation is focused on learning compensation strategies as opposed to recovery of cognitive functions (e.g. learning how to deal with the problems and limitations, but not solving them; Laver, George, Thomas, Deutsch & Crotty, 2015). This is also the case for recovery of activities of daily life (ADL). Furthermore, conventional ABI rehabilitation poses several limitations: it is time consuming, costly, labor and resource intensive, reliant upon the adherence of a patient, limited in availability subject to location, and has a modest effect (Saposnik, 2016).

Research has demonstrated that rehabilitation following ABI can facilitate recovery of cognitive functions, even years following the injury (Miltner, 2016; Laver et al., 2015; Rohling, Faust, Beverly & Demakis, 2009; Cappa et al., 2005; Cicerone et al., 2000, Cicerone et al., 2005). Repetitive, task and goal-oriented training has been shown to improve cognition and ADL on a functional level for those who have experienced an ABI. However, there remains a need for further investigation and the development of rehabilitation protocols or tools that can help in extending conventional rehabilitation to overcome its limitations.

Over the past ten years, research has emerged regarding the use of VR as a rehabilitation tool for ABI, suggesting that it is a feasible and useful option that may improve cognition, ADL, and physical and emotional deficits leading to disability, while reducing costs and resources (Spreij, Visser-Meily, Sibbel, Gosselt & Nijboer, 2020; Spreij, Gosselt, Visser-Meily & Nijboer, 2020; Gamito et al., 2017; Laver et al., 2015). Conventional rehabilitation protocols typically take place in a controlled environment, while VR aims to simulate settings one may encounter in daily life (e.g. possesses higher ecological validity), which may be attributed to an immersive and dynamic setting (e.g. many external distractors and time-pressure) (Negu* et al., 2016; Nijboer, 2017). VR simulations create an environment in which stimuli can be fully controlled and adjusted to a person*s level of functioning (Bohil et al., 2011; Nijboer, 2017). Finally, VR offers the ability to register every individual*s actions, and may serve as a measure of cognitive function on *activity* level (Nijboer, 2017; Rizzo et al., 2004). Therefore, research suggests that VR simulations are a promising addition to rehabilitation following ABI, and that

this will enhance not only cognitive outcomes, but ADL, IADL (instrumental activities of daily living) and quality of life (Qol).

Research has shown that serious games (e.g. the gamification of tasks) and the ability to include incremental levels of difficulty can serve as a motivating factor (Hamari et al., 2014; Hense et al., 2014), increasing the likelihood of intense and repetitive practice in an entertaining method. The current research will allow participants to train cognitive functions following an ABI, using this novel approach: a VR serious game named Koji*s Quest in addition to conventional rehabilitation.

The main aim of the current study is to examine if there is a treatment effect in the cognitive domains assessed in the condition where patients receive a rehabilitation program with conventional therapy plus Koji's Quest, and compare this effect to those receiving only conventional therapy. Furthermore, the current study aims to examine if treatment effects are comparable between inpatient and outpatient groups.

Hypotheses:
1. Inpatient Group: It is expected that complementing conventional rehabilitation by training with Koji's Quest will have a greater treatment effect on cognition than the treatment effect of conventional rehabilitation alone (from T1 to T2).

Outpatient Group: It is expected that complementing conventional rehabilitation by training with Koji's Quest will have a greater treatment effect on level of function in terms of ADL than the treatment effect of conventional rehabilitation alone (from T1 to T2).

2. It is expected that there will be no significant difference in the treatment effects found between inpatient and outpatient groups.

3. It is expected that interactions between scores on the NPO, questionnaires, demographic factors, and medical factors will contribute to the treatment effect observed in both inpatient and outpatient groups.

4. It is expected that effects of training will be robust after a 3 month follow up (T3). It is expected that individuals with ABI will not show further improvement from their most recent testing session (T2), however, will be improved from baseline (T1) in the inpatient group.

5. It is expected that effects of training will be robust after a 3 month follow up (T3). It is expected that individuals with ABI will not show further improvement from their most recent testing session (T2), however, will be improved from baseline (T1) in the outpatient group.

Study objective

Primary objective:

Inpatient Group:
The primary objective of the research with the inpatient group is to assess whether there is a treatment effect in cognition (at T2) compared to baseline (T1) using conventional rehabilitation, as compared to conventional rehabilitation with the addition of training with Koji's Quest.

Outpatient Group:
The primary objective of the research with the outpatient group is to assess whether there is a treatment effect at the level of function in terms of ADL (at T2) compared to baseline (T1) using conventional rehabilitation, as compared to conventional rehabilitation with the addition of training with Koji's Quest.

Secondary objectives:
To examine the extent to which inpatient versus outpatient treatment effects in cognition differ from baseline (T1) to post intervention (T2).

Sub-questions:
- Which factors contribute to whether an individual has a treatment effect or not, e.g., demographic factors, medical factors, performance on neuropsychological tests (NPO), and performance on questionnaires?
- After a 3 month follow up (T3), how robust are the treatment effects for the inpatient group (if any) found compared to T2?
- After a 3 month follow up (T3), how robust are the treatment effects for the outpatient group (if any) found compared to T2?

Study design

The current study is designed as a single-blind randomized controlled trial. Randomization will be done through a block design with a 1:1 allocation ratio. Participants will be assigned to blocks based upon their gender and age. Within the blocks, the participants will be randomly allocated to either the experimental or the control group by computer generated sequences. Block randomization will be completed by a data analyst with no clinical ties to the current study.

The current study is a between-and-within subjects repeated measures trial. We will include 142 ABI inpatients who are currently receiving treatment at a facility, and 142 ABI outpatients who currently are living at home and are either receiving treatment outside of their facility or no treatment.

Both patient groups will consist out of an experimental group (n = 71) and a

control group (n = 71). The control group consists of patients with ABI who will receive conventional rehabilitation, whereas the experimental group will receive conventional rehabilitation concurrently to training with Koji's Quest.

The training tasks associated with each cognitive domain in the VR intervention, Koji's Quest, will be randomized to control for order effects and balance the fatigue associated with time spent during rehabilitation (i.e. if selective attention is always trained first and executive functioning is always trained last, the participant*s training may be impacted by fatigue rather than reflect cognitive ability). The cognitive training software will be programmed to randomly select the order of the cognitive training tasks.
See protocol section 3: Study Design for further details.

Intervention

The ABI inpatient and outpatient groups will either receive solely conventional rehabilitation (control group) or conventional rehabilitation with the addition of training with Koji's Quest (experimental group). The intervention will last for 6 weeks - 3 times per week, in sessions of 30 minutes. Individuals in the control groups will be waitlisted and will be offered the ability to train with Koji's Quest as well following the conclusion of their participation in the study.

Study burden and risks

Participation is voluntary in all subjects and participants are free to withdraw from the study at any time, while still receiving compensation. There are minimal risks associated with participation in this study, namely some individuals may experience dizziness as a result of using virtual reality (VR). All questionnaires and neuropsychological tests administered to both inpatient and outpatient groups will have a maximum duration of 90 minutes. Training sessions using VR will last approximately 30 minutes per session.Both groups may have the benefit of a treatment effect that enhances their cognitive functions and activities of daily life (ADLs) if the intervention is successful. Participants will also be contributing to furthering scientific discovery.

Inpatient group:
Burden and inconvenience are minimal considering the inpatient group will be recruited and participate at the center they are currently undergoing treatment in. Furthermore, to minimize burden, as much information as possible regarding demographics, medical information, and scores on relevant screenings, NPO, and questionnaires will be gathered from electronic patient files (EPFs).

Outpatient group:
Use of the intervention at home will minimally inconvenience the outpatient

group as they will still follow their scheduled conventional rehabilitation, and are able to follow the VR training protocol during times that are suitable for them. Their NPO can be administered by a qualified researcher either at the facility where the outpatient receives treatment, or at their place of residence. Questionnaires can be filled in independently and with a proxy at home as well.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Minimum age of 18
2. Speaking Dutch or English fluently
3. Acquired brain injury (ABI) diagnosed by a neurologist
a. Intracerebral hemorrhage (ICH)

b. Cerebral infarction
c. Subarachnoid hemorrhage (SAH)
d. Transient ischaemic attack (TIA)
e. Traumatic brain injury (TBI; e.g. concussion)
f. Brain tumor (resection)
4. In the subacute (one day to three weeks) or chronic (more than three weeks) phase post-injury
5. Reported cognitive complaints (in our online questionnaire) see Appendix 2 of C1. Research Protocol

Exclusion criteria

1. Unable/incapacity to give permission for participation (IC)
2. Unable or unwilling to use a VR headset/computer screen for test administration
3. In the acute phase post-injury (the first 24 hours)
4. Diagnosed with epilepsy
5. Comprehension disorder, such that participants cannot understand instructions
6. Significant adverse symptoms related to cyber sickness measured by the SSQ in the initial session
7. Participation in other studies during the course of this study
8. Those who have such severe physical deficits so that using a controller is not possible

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	21-11-2022

Enrollment:	284
Type:	Anticipated

Medical products/devices used

Generic name:	Koji's Quest
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-01-2023
Application type:	First submission
Review commission:	METC NedMec

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	NL76422.041.21