Clinical effectiveness of non-confrontational feedback during cognitive rehabilitation: an intervention for improving self-awareness of deficits for people with acquired brain injury

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

Summary

ID

NL-OMON52910

Source
ToetsingOnline

Brief title
Non-confrontational feedback after ABI

Condition

- Other condition

Synonym
ABI, brain damage

Health condition

niet-aangeboren hersenletsel

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Revalidatiefonds

Intervention

Keyword: acquired brain injury, cognitive rehabilitation, non-confrontational feedback, self-awareness of deficits

Outcome measures

Primary outcome

The primary aim of the intervention is to improve self-awareness of deficits.

The main study parameter is change between T0 (baseline) and T6 (12 months after T0) in terms of self-awareness of deficits (SRSI).

The reason for adding additional post-measurements (T1, T2, T3, T4, T5) is twofold. First, adding additional post-measurements increases statistical power (see for example Vickers,2003). Second, adding additional post-measurements makes it possible to look at differences between the control group and experimental group in the course of recovery/response to treatment (e.g. does the experimental group reach a certain level of self-awareness of deficits more quickly than the control group).

Secondary outcome

Secundairy goals are:

- on the short term improve self-awareness of deficits, motivation for rehabiliation treatment and participation in rehabilitation treatment.
Study parameters are changes between T0 (baseline) and T2 (6 weeks after the start of cognitive rehabilitation) in terms of self-awareness of deficits (PCRS, SRSI), motivation for treatment (from the perspective of the patient (MOT-Q) and from the perspective of the therapist (VAS-scale)), and participation in rehabilitation treatment from the perspective of the therapist (PRPS).

- on the long term improve quality of life, social participation and mood.
Study parameters are changes between T3 (3 months after T0) and T6 (12 months after T0) in terms self-awareness of deficits (PCRS), quality of life (SS-QOL-12), social participation (USER-P), mood (HADS-D).

- finally it will be evaluated whether the new intervention is usable from the perspective of rehabiliation professionals als well as patients (in terms of among other things patient satisfaction, burden/worklaod for the patient, length and content of sessions, patient compliance).

Study description

Background summary

At this moment in the Netherlands more than 500.000 people live with the lasting consequences of Acquired Brain Injury (ABI) as a consequence of accidents, strokes, tumors or other causes. Each year another 130.000 people suffer an ABI. For some people the consequences are so severe that rehabilitation treatment is needed. Up to 97% of patients with ABI who receive outpatient or inpatient rehabilitation can suffer from impaired self-awareness of deficits. Patients with impaired self-awareness of deficits have difficulties understanding their strengths and weaknesses. These patients often are less motivated to participate in rehabilitation treatments because they do not see the need for treatment. Partly due to the decreased motivation to participate in rehabilitation treatments patients show less and/or slower progress; rehabiltation outcomes for these patients are unfavourable. Still at this moment rehabilitation settings do not explicitly aim to improve awareness of deficits. There are no evidence-based interventions for improving awareness of deficits.

Study objective

The objective of this study therefore is to investigate the clinical effects and the usability of a new and unique intervention 'nonconfrontational feedback' for improving awareness of deficits. The intervention given at the start of (outpatient or inpatient) cognitive rehabilitation of patients with impaired self-awareness of deficits after ABI.

Study design

A multicenter randomized controlled trial.
There will be seven measurement time points: baseline (T0) before the start of the cognitive rehabilitation; short-term measurements three weeks (T1) and six weeks (T2) after T0; and long -term measurements three months (T3), six months (T4), nine months (T5) and twelve monts (T6) after T0.

Intervention

All patients receive rehabilitation aimed at improving cognitive functioning. Patients will be randomized over 2 conditions:

1) *Non-confrontational feedback*: this group receives from the start of the (outpatient or inpatient) cognitive rehabilitation:
- Structured psycho-education abour possible consequences of brain injury for cogntive functioning, self-awareness of deficits and daily functioning;
- Performance of specific cognitive tasks during the intervention sessions and in real-life settings and/or virtual reality settings;
- Structured multimodal (verbal, visual and audiovisual) feedback according to the socalled 'Socratic method' consisting of (as much as possible) positive reinformcement and non-confrontational discussion between patient and therapist

about how the patient performed a task.

2) *Care as usual: this group receives regular cognitive rehabilitation including the regular feedback as usual.

Study burden and risks

Patients who participate in the study have the same risks as patients that receive usual treatment of the consequences of brain injury. Participation in the study does not lead to additional risks.

The expectation is that the new intervention has a positive effect on self-awareness of deficits, motivation for rehabilitation treatment, participation in rehabilitation treatment, quality of life, social participation and mood.

During the measurements patients are asked to fill out questionnaires (together with the researcher or the therapist). During the measurements there will be enough breaks. In general, filling out the questionnaires is not experiences as stressfull.

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

For patients, inclusion criteria are:
- 18 years or older
- indication for (outpatient or inpatient) cognitive rehabilitation
-diagnosed with ABI (e.g. stroke, traumatic brain injury, hypoxia after cardiac arrest, postoperative brain tumor)
- impaired self-awareness of deficits, based on clinical judgment and score on Patient Competency Rating Scale and/or Self-Regulation Skills Interview.For each patient a significant other participates in the study, for filling out a questionnaire on the patient. Significant others can participate in case they are 18 years or older.

Exclusion criteria

Patient are excluded in case of:
- no informed consent.
- neurodegenerative disease
- insufficient command of the Dutch language
- aphasia.
- visual impairments (that hinder test assessment)
- patient is still in PTA (GOAT>74).
- premorbid psychiatric conditions / substance abuse for which hospital admission was needed Significant others cannot participate in case they are not able to fill out the PCRS due to insufficent command of the Dutch language, or in case of no informed consentinvull

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-08-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-02-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-06-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-08-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 29578
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62948.068.17
Other	registratie vindt plaats na goedkeuring door de METC
OMON	NL-OMON29578