Foutloos Leren bij Goal Management Training.

No registrations found.

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

Summary

ID

NL-OMON22835

Source
NTR

Health condition

Executieve stoornissen na niet aangeboren hersenletsel; Executive disorders after acquired brain injury

Sponsors and support

Primary sponsor: Donders Institute for Brain, Cognition and Behaviour, Centre for Cognition, Radboud University Nijmegen, Nijmegen, The Netherlands
Source(s) of monetary or material Support: Nationaal Initiatief Hersenen & Cognitie (NIHC)

Intervention

Outcome measures

Primary outcome

The primary outcome measure is a standardized scale measuring performance of IADL tasks before and after treatment (int. al. the percent change in the number of correct steps).

Secondary outcome

1. Goal Attainment Scale;

2. DEX (Dysexective Questionnaire): A self-report measure of behavioral difficulties associated with dysexecutive syndrome, administered to the patient and his/her caregiver;

3. EFI-NL (Executive Function Index, Dutch version): A short self-report questionnaire for the assessment of executive functions as encountered in daily life;

4. EOS (Executive Observation Scale): Concerns behavioral and cognitive aspects of executive functioning in daily tasks;

5. CFQ (Cognitive Failures Questionnaire): A measure for subjective cognitive complaints;

6. RAND-36: Measuring health related quality of life.

Study description

Background summary

Rationale:

Brain-injured patients referred for outpatient rehabilitation have difficulties with planning, problem solving and reasoning. These difficulties can be characterized as executive deficits, which can vary from relatively mild to rather severe. Executive deficits lead to real-life everyday disorganization and difficulties in instrumental activities of daily living (IADL tasks).

Goal management training (GMT) is a successful treatment for these deficits and helps to structure activities in daily life. GMT entails learning and applying an algorithm, in which a daily task is subdivided into multiple steps to handle executive difficulties of planning and problem-solving. The acquisition of the algorithm and the steps, however, relies on self control, which is impaired in many patients with executive problems. Consequently, errors that occur during learning the algorithm are not corrected and may interfere with the correct algorithm and the correct steps. Preventing the occurrence of errors during learning, also known as errorless learning, may enhance treatment effects. Both Goal management training and errorless learning are two methods well studied and and demonstrated to be effective. Until now however the two methods have never been combined.

Our hypothesis is that applying errorless learning in Goal management training will contribute to a more effective (re)learning of IADL tasks and thus to a better treatment of executive deficits in cognitive rehabilitation.

Objective:

The primary objective is to examine the efficacy of a combined errorless learning and GMT intervention for treatment of executive problems of patients with acquired brain injury (ABI) in the chronic phase (>6 months post-onset) focusing on instrumental activities of daily living (IADL).
Secondary objectives are the subjective experience of participating patients using Goal Attainment Scaling, self-reported executive functioning and health-related quality of life.

Study design:

The study will be a double blind randomized controlled trial in which the efficacy of GMT with an errorless learning approach will be compared with standard GMT (treatment as usual, no errorless learning but trial and error learning).

Study population:

The study population consists of patients referred for outpatient cognitive rehabilitation. Participants eligible for the study must have executive disorders due to Acquired Brain Injury (ABI) of nonprogressive nature (i.e. TBI, stroke) with a minimal time post-onset of 3 months.

Intervention:

The interventions are based on standard GMT, an evidence based cognitive rehabilitation intervention used for ABI patients with executive problems. In consultation with the therapist, each participant will select two individual IADL-tasks to be learned during the training.

The investigational treatment will have an errorless learning approach meaning that both learning and applying the algorithm of GMT will be taught errorless. This means that the multiple steps of the GMT as well as the actual performance of the IADL-tasks will be taught without the occurrence of errors under guidance of a therapist.
In standard GMT (comparator) errors do occur. Patients will learn to use algorithm and the performance of the tasks using trial and error.

Primary outcome measure:

The primary outcome measure is a standardized scale measuring performance of IADL tasks.

Study objective

The main objective is to examine the efficacy of a combined errorless learning and Goal

Management Training (GMT) intervention for treatment of executive problems of patients with acquired brain injury (ABI) in the chronic phase (>6 months post-onset) focusing on instrumental activities of daily living (IADL). Our hypothesis is that applying errorless learning in Goal management training will contribute to a more effective (re)learning of IADL tasks and thus to a better treatment of executive deficits in cognitive rehabilitation.

To establish the objective GMT with an errorless learning approach will be compared to standard GMT (without errorless learning). The primary outcome measure is the objective assessment of performance on IADL tasks.

Study design

T0: Pre intervention;

T1: Post intervention (6 weeks post TO).

Intervention

The interventions are based on standard GMT, an evidence based cognitive rehabilitation intervention used for ABI patients with executive problems. In consultation with the therapist, each participant will select two individual IADL-tasks to be learned during the training.

The investigational treatment will have an errorless learning approach meaning that both learning and applying the algorithm of GMT will be taught errorless. This means that the multiple steps of the GMT as well as the actual performance of the IADL-tasks will be taught without the occurrence of errors under guidance of a therapist.

In standard GMT (comparator) errors do occur. Patients will learn to use the algorithm and the performance of the tasks using trial and error. The therapist in this group will not be responsible for preventing errors during learning and applying GMT.

Both types of GMT will consist of 8 individual sessions (max. 60 minutes) and will be given twice a week by a trained therapist.

Contacts

Public
Radboud University Nijmegen
Donders Institute for Brain, Cognition and Behaviour
Centre for Cognition (Neuropsychology & Rehabilitation Psychology)
Montessorilaan 3
P.O. Box 9104
Dirk Bertens
Nijmegen 6500 HE

The Netherlands
+31 (0)24 3655935
Scientific
Radboud University Nijmegen
Donders Institute for Brain, Cognition and Behaviour
Centre for Cognition (Neuropsychology & Rehabilitation Psychology)
Montessorilaan 3
P.O. Box 9104
Dirk Bertens
Nijmegen 6500 HE
The Netherlands
+31 (0)24 3655935

Eligibility criteria

Inclusion criteria

1. Age: 18-70 years;

2. Non-progressive acquired brain injury;

3. Minimal time post-onset of 3 months;

4. Outpatient rehabilitation;

5. Living independently at home;

6. Executive deficits (NP assessment);

7. Written informed consent.

Exclusion criteria

1. Inability to speak/understand the Dutch language;

2. Severe psychiatric problems (history);

3. Neurodegenerative disorders;

4. Substance abuse;

5. Severe cognitive comorbidity (i.e. dementia).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2012
Enrollment:	64
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-08-2012
Application type:	First submission

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
NTR-new	NL3417
NTR-old	NTR3567
CCMO	NL38019.091.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A