**NeuroCue*, a randomized controlled study into the use of an electronic cognitive aid in patients with acquired brain injury*

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1. Effectiveness: the study is aimed at increased independence of patients and thereby increasing quality of life and well-being of both patients and caregivers involved. 2. Usability: Use of PDA by patients; frequency and methods of use, prognostic...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON33708

Source
ToetsingOnline

Brief title
PDA-intervention in patients with acquired brain injury

Condition

- Structural brain disorders
- Cognitive and attention disorders and disturbances

Synonym
cognitive disorders after brain injury/problems with memory and planning after brain damage

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: brain injury, cognitive aid, memory and planning, PDA

Outcome measures

Primary outcome

The first primary outcome is effectiveness of the PDA-intervention, measured a.o. as the efficiency on target behaviours measured with an interview. Furthermore, subjective cognitive problems in daily life and social and instrumental activities will be measured with questionnaires Finally, a measure of self-efficacy will be used.

The second primary outcome is *usability* of the device used for the intervention. A semistructured interview will be used to ask the users (patients and caregivers) about their experiences with the use of the PDA. In addition, the log file will be evaluated and the percentage of persons still wanting to use the PDA after 8 and 16 weeks is calculated.

Secondary outcome

Although improvement on neuropsychological test performance is not expected, a pre and post intervention assessment of basic cognitive abilities will be performed .A measure for mood, especially depression after brain injury will be used. Subjective well-being and quality of life are recorded. Finally, some aspects of functioning of the caregiver involved will be assessed: mood (depression), caregiver strain and well-being and quality of life.

Study description

Background summary

In the Netherlands about 200.000 people live with the consequences of stroke and traumatic brain injury. The cognitive, emotional and behavioural consequences of brain injury occur in many people, and lead to severe disabilities, problems with participation in society and long-term care dependency. Cognitive rehabilitation (CR) is an effective form of health care for this group of patients, which enables them to manage, reduce, or live with the probably persistent cognitive deficits. The objectives of CR are to improve a person's functions in domains that are relevant to their everyday lives. The effectiveness can be found in community-reintegration and increased quality of life, by meeting real life demands and positive changes in productivity and subjective well-being. In this research project a new form of CR offered in the community is evaluated, establishing the clinical and societal effectiveness. The intervention entails the use of a personal digital assistant (PDA) for brain injured persons with attention, initiative, memory or planning deficits aimed at the reduction of everyday problems and less dependency on care facilities. The PDA will serve as a reminder or planning system to compensate for reduced cognitive functions. Large scale controlled outcome studies of these systems do not exist. In the proposed study usability and effectiveness will be investigated.

Study objective

1. Effectiveness: the study is aimed at increased independence of patients and thereby increasing quality of life and well-being of both patients and caregivers involved.
2. Usability: Use of PDA by patients; frequency and methods of use, prognostic factors for successful use.

Study design

Single-blind, randomized clinical trial

Intervention

The experimental group will receive the PDA-training for a period of 16 weeks, the control group will receive *care-as-usual*, defined as calendar training or other types of strategy training to cope with their cognitive disabilities Both groups will receive an equal amount of therapy time, namely 15-20 hours in total.

Study burden and risks

This study will have a low burden and has no special risk associated with participation.

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

• Patients with acquired brain injury in either a subacute or a chronic phase
• Patients are referred for cognitive rehabilitation
• Age between 18 and 75 years
• Adequate comprehension of the Dutch language.
- Adequate level of competence
• Problems in daily life functioning as a consequence of brain damage, some degree of insight into their cognitive deficits and an estimated IQ high enough to benefit from this treatment according to the rehabilitation physician or psychologist.

Exclusion criteria

- Visual difficulties incompatible with PDA use
- Serious psychiatric comorbidity
- Progressive disorders, such as Alzheimer*s, Parkinson*s disease and other forms of dementia

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):	15-09-2008
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	25-04-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-10-2008
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-11-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-11-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-03-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-03-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-07-2009
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

No registrations found.

In other registers

Register	ID
CCMO	NL21155.068.08