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

No registrations found.

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

Summary

ID

NL-OMON25631

Source
NTR

Brief title
NeuroCue

Health condition

Acquired brain injury, Stroke, traumatic brain injury, cognitive rehabilitation, personal digital assistant, PDA, quality of life, well being, independence, effectiveness, usability, intervention
Niet-aangeboren hersenletsel, beroerte of hersenbloeding, traumatisch hersenletsel, cognitieve revalidatie, kwaliteit van leven, welzijn, onafhankelijkheid, effectiviteit, gebruiksvriendelijkheid, interventie

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Effectiveness of the PDA-intervention: The first primary outcome is the efficiency on target behaviours measured with an interview. Furthermore, subjective cognitive problems in daily life, self-efficacy and social and instrumental activities will be measured.

Usability of the PDA-intervention: The second primary outcome are the experiences of patients and caregivers with the use of the PDA. The effective use of the device will also be evaluated.

Secondary outcome

• levels of distress and depression for the user

• levels of distress, strain and depression for the caregivers

• quality of life for patients and close family members

Study description

Background summary

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

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. And thereby increasing quality of life and well-being of both patients and caregivers involved.

Study design

There will be 5 measurements during the intervention for each patient.

A double baseline (two and zero weeks before the intervention), and measurements at 8 and 16 weeks after the start of the intervention.

A follow-up measurement is performed 3 months after the intervention has ended.

Intervention

During the baseline period (2 weeks) target behaviours are determined for all participants. The experimental group will receive the PDA 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.

Contacts

Public
School for Mental Health and Neuroscience
Maastricht University, DrT 12, room 4.E3.013
p.o. box 616

E.A. Joode, de
Maastricht 6200 MD
The Netherlands
+31 (043) 3884113
Scientific
School for Mental Health and Neuroscience
Maastricht University, DrT 12, room 4.E3.013
p.o. box 616

E.A. Joode, de
Maastricht 6200 MD
The Netherlands
+31 (043) 3884113

Eligibility criteria

Inclusion criteria

1. Patients with acquired brain injury in either a subacute or a chronic phase

2. Patients are referred for cognitive rehabilitation

3. Age between 18 and 75 years

4. Adequate comprehension of the Dutch language.

5. Experienced problems in daily life functioning as a consequence of brain damage; insight into cognitive deficits; sufficient IQ level to benefit from treatment -- all according to the rehabilitation physician or psychologist.

Exclusion criteria

1. Visual difficulties incompatible with PDA use

2. Serious psychiatric comorbidity

3. 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	128
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-03-2008
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	NL1174
NTR-old	NTR1219
Other	MEC : 08-3-007
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A