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

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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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25631

Bron
NTR

Verkorte titel
NeuroCue

Aandoening

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

Ondersteuning

Primaire sponsor: Universiteit Maastricht
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2008
Aantal proefpersonen:	128
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1174
NTR-old	NTR1219
Ander register	MEC : 08-3-007
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A