Cognitive rehabilitation in brain tumor patients after neurosurgery

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OBJECTIVE: To evaluate the immediate and longer-term effects of early cognitive rehabilitation on cognitive performance and self-reported symptoms/functioning in patients with low-grade gliomas and meningiomas, in a prospective randomized trial....

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

Samenvatting

ID

NL-OMON29674

Bron
NTR

Verkorte titel
COG REHAB

Aandoening

Cognitive deficits
Brain tumor

Ondersteuning

Primaire sponsor: St. Elisabeth Hospital Tilburg, Tilburg University
Overige ondersteuning: Zon-Mw, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Feasibility (adherence, patient experience, attrition) and cognitive functioning (group and individual neuropsychological performance, as assessed with the computerized battery of neuropsychological tests and the two additional neuropsychological tests) and magnitude of change over time.

Toelichting onderzoek

Achtergrond van het onderzoek

Deficits in cognitive function are common in patients with primary brain tumors. Remarkably few studies have been
directed towards the rehabilitation of the cognitive deficits in brain tumor patients. The purpose of the proposed project is to evaluate the immediate and longterm
effects of cognitive rehabilitation in a prospective randomized trial on neuropsychological test performance and selfreported cognitive symptoms, psychological symptoms (anxiety and depression), fatigue, professional functioning and community integration. In the first 6 months of the project a feasibility study will be conducted to ensure that adherence, patient experience, and
potential attrition are according to our expectations.
Subsequently, a prospective randomized (waitinglist)
controlled trial (RCT) will be performed. In the RCT, patients are randomized to early cognitive rehabilitation (3 months after surgery) or to a waitinglist
control condition. Outcome assessment of cognitive performance and selfreported symptoms/functioning will be prior to surgery, before cognitive rehabilitation (3 months), immediately after cognitive rehabilitation (6 months), and at halfyear follow up (12 months postsurgery), and at similar intervals for the waitinglist
control group.

Doel van het onderzoek

OBJECTIVE: To evaluate the immediate and longer-term effects of early cognitive rehabilitation on cognitive performance and self-reported symptoms/functioning in patients with low-grade gliomas and meningiomas, in a prospective randomized trial.

HYPOTHESIS: Cognitive rehabilitation after brain tumor surgery has both immediate and longer-term beneficiary effects on cognitive functioning and patient-reported outcomes.

Onderzoeksopzet

At several time points during the RCT, patients will be tested with the computerized test battery (for cognition; CNS VS), two additional cognitive tests and several self-report questionnaires. Testing is done prior to surgery, prior to cognitive rehabilitation (3 months), immediately after cognitive rehabilitation (6 months) and at half-year follow up (12 months post-surgery).

Onderzoeksproduct en/of interventie

Evidence-based cognitive rehabilitation program that is provided via a tablet app. The program aims both retraining, and teaching and practicing of compensational strategies of attention, memory and executive functioning. Patients spend 3 hours per week during 2.5 month in a home-based program. They are monitored and supervised by a trainer. The waitinglist control group will be offered the same cognitive rehabilitation program after they have
undergone all study assessments.

Contactpersonen

Publiek

Tilburg University - department of Cognitive Neuropsychology - Simon building - room S 219

Karin Gehring
PO Box 90153

Tilburg 5000 LE
The Netherlands
phone: +31 13 466 2408

Wetenschappelijk

Tilburg University - department of Cognitive Neuropsychology - Simon building - room S 219

Karin Gehring
PO Box 90153

Tilburg 5000 LE
The Netherlands
phone: +31 13 466 2408

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The adult patient has a brain tumor that is radiologically suspect for either a meningioma or

low grade glioma*; The patient will undergo craniotomy for the brain tumor; The patient is in clinical reasonable or good condition (Karnovsky performance Scale >=70).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

History of intracranial neurosurgery; history of severe psychiatric or neurological disorders; lack of basic proficiency in Dutch; IQ below 85, or (very)
low cognitive skills; Karnovsky Performance Scale under 70; complete unfamiliarity with the use of computers; surgery-related complication; insufficient reading skills.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2015
Aantal proefpersonen:	152
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-09-2015
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	NL5285
NTR-old	NTR5392
Ander register	ZonMw projectnumber 842003009 : METC Brabant protocol P.1449

Resultaten