GRIP op vermoeidheid

Gepubliceerd: 14-06-2020 Laatst bijgewerkt: 15-05-2024

It is hypothesized that bCBT for severe fatigue will lead to clinical improvements in fatigue levels compared to usual care.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestart
Type aandoening	Neurologische aandoeningen NEG
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26739

Bron
Nationaal Trial Register

Verkorte titel
GRIP on fatigue

Aandoening

- Neurologische aandoeningen NEG

Aandoening

Diffuse glioma

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Prof. dr. Martin Klein
Overige ondersteuning: Stichting Cancer Center Amsterdam

Onderzoeksproduct en/of interventie

- Psychosociale interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the CIS-fatigue score at fourteen weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study: Between 80% and 90% of patients with primary brain tumors experience fatigue that persists in one-third of patients for months and years after therapy. Up to 40% of fatigued brain tumor patients regard it as severe.Blended Cognitive Behavioral Therapy (bCBT), i.e. a combination of face-to-face sessions and web-based CBT, has been shown to be effective in reducing severe fatigue in several clinical populations, but not in patients with primary brain tumors. Objective of the study: To investigate the efficacy of bCBT compared to usual care in severely fatigued patients with primary brain tumors. Study design: This study is a monocenter randomized controlled clinical trial. At baseline, patients will be randomized to bCBT or care as usual. Study population: 100 adult patients with clinically stable primary brain tumors and severe fatigue (CIS20 subscale subjective fatigue ≥ 35) will be recruited. Intervention: BCBT consists of 5 patient-therapist contacts, either face-to-face, or via video-consultation and information and assignments in 5 to 8 web-based therapy modules delivered via an internet portal (Minddistrict) and supported by email contact with a therapist providing feedback on the progress made by the patient. The CBT will be applied by trained psychologists. Primary study parameters of the study: Fatigue severity at 14 weeks after randomization as measured by the CIS20 subscale subjective fatigue will be the primary outcome. Secondary study parameters of the study: The set of secondary study parameters, bearing potential to measure and predict treatment effects, will consist of questionnaires concerning quality of life and functioning, neuropsychological testing, neurological assesment, advanced neuroimaging and clinical parameters (tumor location, undergone previous treatments, medication use). The set of determinants, and primary and secondary outcomes will be measured at baseline and after the intervention at fourteen weeks. Ten weeks after the measurement the questionnaires will be completed again.

Doel van het onderzoek

It is hypothesized that bCBT for severe fatigue will lead to clinical improvements in fatigue levels compared to usual care.

Onderzoeksopzet

T0: Baseline before intervention T1: fourteen weeks after baseline T2: twentyfour weeks after baseline

Onderzoeksproduct en/of interventie

GRIP on fatigue is a multimodal Dutch intervention with therapist sessions and online modules with therapist feedback. BCBT for cancer related fatigue in patients with a PBT is directed at beliefs and behaviour of the patients that contribute to the persistence of fatigue. The intervention lasts twelve weeks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

a. ≥ 18 years of age b. histological diagnosis of primary brain tumor c. severely fatigued (CIS20 subscale subjective fatigue ≥ 35) d. stable disease, i.e. no oncological treatment for ≥ 2 months prior to inclusion e. expected survival ≥ 3 months f. no signs of radiological or clinical tumor progression g. no corticosteroid use h. exclusion of other causes of fatigue

other than brain tumor treatment, such as anemia or infection i. able to speak, read and write Dutch j. having access to a computer with internet

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

a. depression b. primary sleep disorders c. current psychological treatment for a psychiatric disorder d. current pregnancy or having given birth in the past 3 months e. pharmacological treatment for fatigue that was started in the past 3 months (e.g. Amantadine, Modafinil, Ritalin, Pemoline) f. Karnofsky performance score <70

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Verzorging

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-06-2020
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Goedgekeurd WMO

Datum:	29-05-2020
Soort:	Eerste indiening
Toetsingscommissie:	MEC Academisch Medisch Centrum (Amsterdam)
	Kamer G4-214
	Postbus 22660
	1100 DD Amsterdam
	020 566 7389
	mecamc@amsterdamumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55287
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8711
CCMO	NL71503.029.19
OMON	NL-OMON55287

Resultaten