GRIP on fatigue

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

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON26739

Source
Nationaal Trial Register

Brief title
GRIP on fatigue

Condition

- Neurological disorders NEC

Health condition

Diffuse glioma

Research involving
Human

Sponsors and support

Primary sponsor: Prof. dr. Martin Klein
Source(s) of monetary or material Support: Stichting Cancer Center Amsterdam

Intervention

- Psychosocial intervention

Explanation

Outcome measures

Primary outcome

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

Secondary outcome

The set of secondary outcomes consists of several symptoms measured by questionnaires at baseline, fourteen weeks and twentyfour weeks, including depression, HRQOL and anxiety and objective neurocognitive functioning.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Supportive care

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-06-2020
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	29-05-2020
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 55287
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results