A blended eHealth intervention for sleep-disorders after acquired brain injury

Published: 12-10-2017
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The main objective of this study is to evaluate the efficacy of an eHealth cognitive behavioural intervention to treat insomnia in people with acquired brain injury.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON46579

Source
ToetsingOnline

Brief title
eCGT-I ABI

Condition

- Sleep disorders and disturbances

Synonym
sleepdisorders, sleeping problems

Research involving
Human

Sponsors and support

Primary sponsor: Heliomare Revalidatie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: brain injury, eHealth, insomnia, sleep disorder

Outcome measures

Primary outcome

The primary outcome measure is the change in insomnia severity.

Secondary outcome

Secondary outcome measures are the change in fatigue, emotional well-being,

subjective cognitive functioning and participation.

Study description

Background summary

Internet delivered cognitive behavioural therapy is effective in improving sleep in the general population. Since cognitive behavioural therapy is also effective for sleep disorders after acquired brain injury, eHealth seems to be a suitable intervention for this group as well. As far as we know, no study has been performed on the efficacy of internet delivered cognitive behavioural therapy for insomnia after brain injury.

Study objective

The main objective of this study is to evaluate the efficacy of an eHealth cognitive behavioural intervention to treat insomnia in people with acquired brain injury.

Study design

A multicenter single blind Randomized Controlled Trial (RCT) will be used, in which the treatment group will receive the eHealth CBT treatment for insomnia and the control group will receive treatment as usual, not specifically aimed at insomnia.

Intervention

The eHealth intervention (CBT) for sleep complaints after acquired brain injury consists of 6 eHealth sessions combined with 2 face-to-face sessions given on a weekly basis to the treatment group. The total duration of the treatment is 6 weeks.

Study burden and risks

Measurements and treatment in this study do not have adverse consequences for those involved, and there are no risks or burden associated with participation. The mental burden will be minimal; participants have to fill in questionnaires at 3 occasions in a 3-months period. The treatment group additionally has to do daily registrations in a sleep diary-app for 8 weeks. The treatment group will be counseled by the psychologist involved. The control group will receive *treatment as usual*, after study completion they will be offered the same eHealth intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

-Acquired Brain Injury diagnosis (Traumatic Brain Injury, Stroke, Brain Tumor)
- Insomnia according to DSM-5 criteria
- Insomnia Severity Index > 10
- 18 years or older

Exclusion criteria

- Untreated sleep-apnea
- Current treatment or expected treatment during the study with main focus on fatigue or sleep (such as the CBT group therapy: *omgaan met beperkte belastbaarheid*).
- Major untreated or unstable medical or psychiatric comorbid condition (eg, epilepsy, psychosis)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2018
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20225
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63014.018.17
OMON	NL-OMON20225