A blended eHealth intervention for insomnia following acquired brain injury

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20225

Source
NTR

Health condition

insomnia, sleep disorder, acquired brain injury, TBI, stroke, CBT-I, eHealth

Sponsors and support

Primary sponsor: Heliomare R&D
VU University Amsterdam
Source(s) of monetary or material Support: Heliomare Research and Development

Intervention

Outcome measures

Primary outcome

1. Insomnia Severity (ISI and sleep diary)

Secondary outcome

1. Sleep quality (Pittsburgh Sleep Quality Index)

2. Sleep related behaviors (SRBQ)

3. Dysfunctional belief and attitudes about sleep (DBAS)

4. Fatigue (Dutch Multifactor Fatigue Scale)

5. Emotional well-being (HADS)

6. Subjective cognitive functioning(CFQ)

7. Participation (USER-Participation)

Study description

Background summary

Online versions of cognitive behavioural therapy for insomnia in the general population have been developed to reach a larger group of patients with insomnia and to create easier access to treatment. Recent reviews show that internet delivered CBT is effective in improving sleep in adults with insomnia in the general population (Seyffert et al., 2016; Zachariae, Lyby, Ritterband & O'Toole, 2016). 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 (Nguyen et al., 2017; Theadom et al, 2017). 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 objective

The main objective of this study is to evaluate the efficacy of the blended eHealth cognitive behavioural intervention as an additional treatment to treat insomnia (e-CBT-I) in people with acquired brain injury.

The main research questions are:
1. Will the e-CBT-I result in a significant reduction of insomnia in people with acquired brain injury compared to a control group with treatment as usual, not specifically aimed at insomnia?
2. Does the treatment group improve more on subjective cognitive functioning, emotional well-being and participation than the control group?

Firstly, we expect to confirm that e-CBT-I is effective in the treatment of insomnia after brain injury. Secondly, we expect that treatment will improve subjective cognitive functioning, emotional well-being and (social) participation.

Study design

pre-measure (week 0), post-measures (week 7), 6-week follow-up (week 13)

Intervention

The eHealth CBT treatment for insomnia after acquired brain injury is based on well-established CBT for insomnia in the general population and includes educational, behavioural and cognitive techniques. These techniques include sleep hygiene education, stimulus control, sleep restriction, cognitive restructuring, activation, relaxation, fatigue- and stress management. The eHealth CBT treatment for insomnia has been adjusted to ABI in content and way of displaying information.

Contacts

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Eligibility criteria

Inclusion criteria

1. Acquired Brain Injury diagnosis (Traumatic Brain Injury, Stroke)

2. Insomnia according to DSM-5 criteria

3. Insomnia Severity Index > 10

4. 18 years or older

5. Comprehension of Dutch language

6. Cognitive capable of using the internet

7. Regular internet access

8. Referred to an outpatient centre

Exclusion criteria

1. Untreated sleep-apnea

2. Current treatment or expected treatment during the study with main focus on fatigue or sleep

3. Alcohol abuse or drugs abuse

4. Major untreated or unstable medical or psychiatric comorbid condition (eg, epilepsy, psychosis)

5. Unstable medication regiments or medication known to produce insomnia.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2017
Enrollment:	76
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-03-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46579
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6895
NTR-old	NTR7082
CCMO	NL63014.018.17
OMON	NL-OMON46579

Study results

Summary results
N/A