A blended eHealth intervention for insomnia following acquired brain injury

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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...

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

Samenvatting

ID

NL-OMON20225

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Heliomare R&D
VU University Amsterdam
Overige ondersteuning: Heliomare Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Insomnia Severity (ISI and sleep diary)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2017
Aantal proefpersonen:	76
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-03-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46579
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A