The treatment of anxiety and depressive symptoms after acquired brain injury.

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

Samenvatting

ID

NL-OMON23617

Bron
NTR

Verkorte titel
BrainACT

Aandoening

Acquired brain injury (ABI), Anxiety, Depression Niet aangeboren hersenletsel (NAH), Angst, Depressie

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome measure for clinical effectiveness is the Hospital Anxiety and Depression

Scale (HADS) measuring depressive and anxiety symptoms. Primary outcome measure for the cost effectiveness will be the five-dimensional five-level EuroQol (EQ-5D-5L) and a cost-questionnaire specifically designed for this study.

Toelichting onderzoek

Achtergrond van het onderzoek

Following an acquired brain injury people frequently experience anxiety and depressive symptoms. Effective treatments for these symptoms are limited. A promising and upcoming therapy is acceptance and commitment therapy (ACT). ACT is a third wave behavioral therapy. The goal of this therapy is not to reduce symptomatology but focusses on the improvement of psychological flexibility. The aim of this study is to investigate the effectiveness of an adapted ACT intervention for people with acquired brain injury who experience anxiety and/or depressive symptoms.

Doel van het onderzoek

The acceptance and commitment therapy will lead to a greater reduction of depressive and anxiety symptoms in compared to a psycho-education intervention.

The acceptance and commitment therapy will lead to less the additional costs and additional outcomes in relation to the psycho-education intervention. (economic evaluation)

The acceptance and commitment therapy will lead to higher levels of psychological flexibility, valued living, and cognitive defusion compared to psycho-education. (clinical effectiveness 'does it work', secondary process-oriented measures)

The acceptance and commitment therapy will lead to higher levels of participation and quality of life, compared to psycho-education. (clinical effectiveness 'does it help', outcome-oriented, secondary measures).

Onderzoeksopzet

All outcome measures are collected at baseline (T0), after one month (T1; during treatment) and after four months (T2; post treatment). At seven (T3) and 12 months (T4) there are follow up measurements.

Onderzoeksproduct en/of interventie

The participants receive Acceptance and Commitment Therapy or psycho-education combined with relaxation training. Both interventions consist of eight sessions which will last 60 till 90 minutes.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- having sustained any type of stroke or traumatic brain injury which is objectified by a neurologist;
- the depression subscale of the Hospital Anxiety and Depression Scale (HADS) is above 7 and/or the anxiety subscale of the HADS is above 7;
- being 18 years or older;

- stable use of medication (such as antidepressants) for the duration of the study and use of antidepressants should be stable four weeks prior to the beginning of the study;
- access to the internet and a computer because treatment materials such as patient videos are shown via the internet;
- the Dutch language, cognitive and communicative skills are sufficient to benefit from treatment based on clinical judgement; and
- giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- history of brain injury or disease (objectified by neurologist and classified as moderate or severe) or any neurological disorder (such as: idiopathic epilepsy, brain tumor, meningioma, multiple sclerosis, Huntington's disease, Parkinson's disease, meningitis, or encephalitis) other than a stroke and traumatic brain injury;
- pre-morbid disability as assessed with the Barthel Index (score<19/20);
- severe co-morbidity that might affect outcome (e.g., cancer or major psychiatric illnesses for which treatment is given at the moment of inclusion);
- ongoing mood and/or anxiety disorder based on the DSM 5 for which pharmacological and/or psychological treatment was necessary during the onset of the brain injury;
- attendance in a previous ACT intervention for comparable problems in the year proceeding entry in the current study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2018

Aantal proefpersonen:	94
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-03-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50203
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6916
NTR-old	NTR7111
CCMO	NL65349.068.18
OMON	NL-OMON50203

Resultaten