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

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

Summary

ID

NL-OMON23617

Source
NTR

Brief title
BrainACT

Health condition

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

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcome measures are the Depression Anxiety Stress Scale (DASS-21), Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P), Short Form Survey (SF12), Acceptance and Action Questionnaire II (AAQ-II), Acceptance and Action Questionnaire after brain injury (AAQ-ABI), Valued Living Questionnaire (VLQ) and the Cognitive Fusion Questionnaire (CFQ-7).

Study description

Background summary

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.

Study objective

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).

Study design

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.

Intervention

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.

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2018
Enrollment:	94
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-03-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50203
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results