Clinical and cost-effectiveness of Acceptance and Commitment Therapy for depression and anxiety after acquired brain injury

Published: 18-07-2018
Last updated: 15-05-2024

Examining the clinical and cost-effectiveness of ACT for individuals with ABI who experience depressive and/or anxiety symptoms.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50203

Source
ToetsingOnline

Brief title
BrainACT

Condition

- Other condition

Synonym
'brain dammage' en 'acquired brain injury (ABI)'

Health condition

Hersenletsel patiënten met angst en/of depressie klachten

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Acceptance and Commitment Therapy, Acquired brain injury, Anxiety, Depression

Outcome measures

Primary outcome

Primary outcome measure for clinical effectiveness is the Hospital Anxiety and Depression Scale (HADS) measuring anxiety and depressive symptoms and the Depression Anxiety Stress Scale (DASS-21) measuring depression, anxiety and stress. 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 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

Acquired brain injury (ABI) causes a wide variety of symptoms and frequently leads to emotional disturbances. Research has shown that patients with ABI experience high levels of anxiety and depressive symptoms. However, to date

effective treatments for these patients are lacking; both cognitive behavioral therapy (CBT) and pharmacological treatments have shown disappointing results in this patient population. A promising and upcoming therapy is Acceptance and Commitment Therapy (ACT). ACT is a third wave behavioral therapy which does not focus on symptom reduction, but on the improvement of psychological flexibility. In contrast to CBT the dysfunctional cognitions of the patient are not changed or challenged during an ACT treatment. ACT helps them to become aware of their thoughts and emotions, and to accept them for what they are. This may be a better fitting approach for patients with ABI since their thoughts are often realistic. ACT has shown positive results in patients suffering from depression, anxiety, obsessive compulsive disorder, psychosis, and chronic pain. The studies examining the effectiveness of ACT for individuals with ABI are, however, very limited.

Study objective

Examining the clinical and cost-effectiveness of ACT for individuals with ABI who experience depressive and/or anxiety symptoms.

Study design

Single-blind multicenter randomized controlled trial (RCT) in which ACT is compared to an active control group (psycho-education intervention combined with relaxation exercises). Participants will be stratified according to type of brain injury (i.e. stroke and traumatic brain injury) and location (hospital).

Intervention

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

Study burden and risks

The burden for the participants is considered to be limited. Patients will have to come to the hospital eight times for the individual therapy or psycho-education sessions (and make homework) as part of their regular treatment and five times to fill out several questionnaires. There is no physical or physiological discomfort associated with participation. Furthermore, a reduction of depressive and anxiety symptoms is expected for participants in both the control as the ACT condition.

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

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 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2019
Enrollment:	94

Type:	Actual

Ethics review

Approved WMO Date:	18-07-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-02-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-05-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-07-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-07-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-09-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-11-2019
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-12-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 23617
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65349.068.18
OMON	NL-OMON23617