A new perspective: Development of a cognitive behavioral therapeutic intervention for patients with remaining trauma related symptoms

Published: 08-03-2023
Last updated: 10-01-2025

The goal of the study is to explore the effects on quality of life of an experimental treatment module that attempts to change trauma related attributions and cognitions in patients with remaining PTSD symptoms.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON53700

Source
ToetsingOnline

Brief title
A cognitive perspective on remaining trauma related symptoms

Condition

- Anxiety disorders and symptoms

Synonym
post-traumatic stress disorder, PTSD

Research involving
Human

Sponsors and support

Primary sponsor: Reinier van Arkelgroep (Den Bosch)

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: attribution style, CBT, PTSD, traumarelated cognitions

Outcome measures

Primary outcome

Self-report questionnaires are used to measure quality of life (MANSA-12vn),

attribution style (experimental questionnaire), trauma related cognitions

(PTCI), and trauma related symptoms (PCL-5).

Secondary outcome

N.A.

Study description

Background summary

There is a fairly large group of patients who suffer from trauma related symptoms, even after receiving trauma-focused treatment. An explanation for this may be found in cognitive factors such as attribution style, the tendency of humans to explain unusual, unwanted and unexpected events in terms of cause and consequence, and posttrauma cognitions. Changing trauma related attributions and cognitions seems to be important for decreasing trauma related symptoms and improving quality of life. An intervention for patients who do not benefit from evidence-based trauma treatment which can contribute to a meaningful and qualitatively better existence is missing. The project team wishes to fulfill this need by developing a treatment module. The effectivity of this treatment module is investigated through this study.

Study objective

The goal of the study is to explore the effects on quality of life of an experimental treatment module that attempts to change trauma related attributions and cognitions in patients with remaining PTSD symptoms.

Study design

The study is a randomized controlled trial on the effect of an experimental treatment module for patients with remaining trauma related symptoms. The study is quantitative in nature.

Intervention

Based on available literature and multidisciplinary guidelines, an experimental treatment module has been developed. A treatment protocol has been drafted stating the content of all sessions. The treatment protocol will remain unchanged from the start until the end of the study. The experimental treatment module is focused on changing attribution style, using cognitive behavioral therapy as a theoretical framework. The experimental treatment module is also in line with the concept of 'positive health' and contains pragmatic social interventions.

Study burden and risks

Participants participate in this study on a voluntary basis. Prior to participatation, expectations are clarified. Specifically, participants are informed that they will have to fill in some additional questionnaires besides regular Routine Outcome Monitoring measures. The extra burden in time for these questionnaires is 10 minutes per assessment. Participation in the experimental treatment module requires physical presence of the participants and active participation during the sessions and between the sessions. The total duration in time is 17 hours over 24 weeks. The physical burden on participants is minimal. As for the mental burden, the experimental treatment module requires participants' attention, concentration and commitment. Besides filling in the questionnaire and physical presence and participation during the treatment sessions, there is no other burden. Risks for damage to health is deemed minimal.

Contacts

Public
Reinier van Arkelgroep (Den Bosch)

Bethaniestraat 10
's-Hertogenbosch 5211LJ
NL
Scientific
Reinier van Arkelgroep (Den Bosch)

Bethaniestraat 10
's-Hertogenbosch 5211LJ

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- All participants are adult (18-63 years)
- All adutls are competent
- All participants have undergone trauma focused treatment
- Despite this treatment, participants continue to experience trauma related symptoms (PCL score of 33 or more)

Exclusion criteria

- Participants who do not have trauma related symptoms
- Participants whose attitude towards the intervention is not in line with the goal of the study (e.g. participant primarily expects symptom reduction instead of improvement in quality of life)
- Participants who do not have sufficient mastery of the Dutch language
- Participants who show an acute high risk for suicide
- Participants who actively and excessively use substances
- Participants who show behavioral problems causing interpersonal conflicts and/ or disturbing the group proces
- Participants who are suspected to or diagnosed with simulation (as demonstrated by clinical asessment)
- Participants whose mental capacity is limited (as demonstrated by clinical asessment)
- Participants whom have a psychological/psychotherapeutic treatment during the experimental intervention
- Participants of which their medication is altered during the experimental intervention

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-07-2023
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2023
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL81918.068.22