

Body oriented interventions to help regulation of arousal for people with problems related to psychotrauma

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The project evaluates an intervention aimed at arousal regulation. The research questions are:- Is there an improvement in signaling body signals and in arousal regulation after following this program?- Does this also lead to positive changes in...

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

Summary

ID

NL-OMON53781

Source

ToetsingOnline

Brief title

Arousal regulation in PTSD

Condition

- Anxiety disorders and symptoms

Synonym

Psycho trauma, PTSD

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: ZONMW

Intervention

Keyword: arousal regulation, body-oriented, psycho trauma, single case study

Outcome measures

Primary outcome

- Hypo- and hyperarousal
- Experienced contact with the body (body awareness)

Secondary outcome

- The trauma- and dissociation-related measures that indicate the severity of the participants' symptoms
- The outcomes with regard to social connection and social functioning, empowerment and quality of life.

Study description

Background summary

Clients with trauma-related problems often suffer from problems in arousal regulation, which are the result of a chronic dysregulation of the stress system. The arousal level may be too high, hyperarousal. This is reflected in a continuous feeling of fear and increased alertness, regularly also in aggressive behaviour. On the other hand, there may be too low arousal, or hypoarousal. Contact with one's own body is often greatly reduced and there is dissociation. Problems in arousal regulation are currently moderately addressed within the regular treatment offer. However, these problems do have a significant impact on daily functioning. That is why specific attention is important. This is also emphasized by clients, who state that additional body-oriented treatments aimed at restoring contact with the body and skills in arousal regulation are necessary. There are indications that a body-oriented approach is suitable for learning to regulate arousal and that other PTSD symptoms also decrease after such an offer. However, the intervention is hardly standardized and there is also little insight into the results.

Study objective

The project evaluates an intervention aimed at arousal regulation.

The research questions are:

- Is there an improvement in signaling body signals and in arousal regulation after following this program?
- Does this also lead to positive changes in daily life, such as the experienced direction and contact with one's own body.

Study design

The treatment is distributed and evaluated at two institutions for trauma treatment: Heelzorg Psychotrauma in Zwolle and Transit Psychotrauma, part of GGZ Centraal, in Ermelo.

For the evaluation we use a mixed method design:

- A quantitative N=1 study with multiple baseline across subjects, using repeated measures during the baseline (with varying duration per individual), the intervention period (8 weeks) and the follow-up (12 weeks). Such an approach is in line with practice.
- In qualitative interviews, themes such as giving meaning to control over one's own body, restoring contact with one's own body and its influence on intimate and social contacts are discussed. These themes cannot be addressed sufficiently through questionnaires.

Intervention

In collaboration with clients, psychomotor therapists have developed a body-oriented intervention of eight weekly sessions to improve arousal regulation. The offer is integrated into the regular treatment, in such a way that there is as little disruption as possible to the usual treatment practice, but that a new and relevant treatment offer is added.

Study burden and risks

The intervention that is offered concerns a standardized range of treatment elements that are already present in treatment practice. For this reason, the risk is not increased compared to regular treatment. The burden on the clients also consists of filling in two questionnaire four times (total 20 minutes each time), a few questions every week (5 minuten) and participating in an interview after the module (60 minutes). In practice, such deployment is not experienced as a great burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- In treatment at one of the two participating centers because of severe traumatic experiences in the past and diagnosed with Post Traumatic Stress Disorder (PTSD), Dissociative Identity Disorder (DID) or Other Specified Dissociative Disorder (OSDD).
- Problems with arousal regulation, with the client and practitioner agreeing that the arousal regulation module could be a suitable addition to the treatment.
- Informed consent from client to participate in the study

Exclusion criteria

There are no predetermined exclusion criteria other than the judgment of the coordinating practitioner or responsible psychiatrist who can decide in individual cases that a client cannot participate.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	13-02-2023
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO	
Date:	14-02-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL82462.042.22