IMPACT-study
Improving PTSD treatment for adults with childhood trauma

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The aim of this project is to investigate the (cost)effectiveness of two innovative forms of trauma-focused therapy for patients with CA-PTSD. The effects will be assessed post-treatment and after a 6 and 12 months follow-up in an intention-to-treat...

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

Summary

ID

NL-OMON55398

Source
ToetsingOnline

Brief title
IMPACT-study

Condition

- Anxiety disorders and symptoms

Synonym
Posttraumatic Stress Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W,Innovatiefonds Zorgverzekeraars

Intervention

Keyword: childhood abuse, prolonged exposure, PTSD, treatment effect

Outcome measures

Primary outcome

PTSD symptom severity.

Secondary outcome

Responder rate (Jacobson & Truax criteria), dropout rate, depression severity,

emotion regulation skills; interpersonal skills; self-concept and quality of

life.

Study description

Background summary

In the Dutch treatment guidelines for anxiety disorders, trauma-focused treatment such as Prolonged Exposure (PE), is recommended as first treatment option for PTSD. However, despite these clear guidelines, there is an ongoing debate among researchers and clinicians whether these guidelines fit patients with childhood abuse related PTSD (CA-PTSD). Non-attendance and high dropout rates in this particular patient group seem common. The general aim of the present project is to test the effectiveness and tolerability of two innovative forms of trauma-focused treatment in patients with chronic, childhood-related PTSD: phase-based therapy (emotion regulation skills training followed bij PE; STAIR/PE) and intensive PE (i-PE). We expect both treatment innovations to have fewer dropouts, to lead to faster symptom reduction and more favorable long term outcomes and consequently, lower treatment costs.

Study objective

The aim of this project is to investigate the (cost)effectiveness of two innovative forms of trauma-focused therapy for patients with CA-PTSD. The effects will be assessed post-treatment and after a 6 and 12 months follow-up in an intention-to-treat analysis. Results will be disseminated and included in treatment guidelines. The ultimate goal is to improve quality of care and contribute to treatment innovation for this severely ill target population.

Study design

Multicenter randomized controlled trial.

Intervention

STAIR/PE: 8 weekly sessions skills training, 8 sessions PE.
i-TFT: TFT delivered in 12 sessions over the course of 4 weeks, and 2 booster sessions.

Study burden and risks

Each participant will receive treatment. Based on previous results, it is expected that all three conditions will be effective for patients. No significant risks are associated with participation. In case of symptom persistence or increase contact with a therapist or an independent expert and doctor (psychiatrist) is available for participants. The burden for patients involve additional measurements. Benefits of participation are extended diagnostic and evaluative information, reduction of mental health issues as symptoms of PTSD and depression and knowledge on specialized treatments for this patient group.

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

-Age >= 18 years
-Multiple traumata related to childhood sexual/physical abuse that occurred <= 17 years of age, and committed by a primary caretaker or an authority figure as index event
-Diagnosis of PTSD according to DSM-5, including at least one specific discrete memory of a traumatic event
- PTSD Symptom severity: CAPS score > 50.
- Sufficient fluency in Dutch to complete the treatment and research protocols.

Exclusion criteria

- Involved in legal procedures concerning admission or stay in The Netherlands
- Pregnancy
- Severe non-suicidal self-injury (NSSI) in the last two months (hospital referral required)
- Severe suicidality
- Alcohol or drug dependence/abuse in last 2 months
- Cognitive impairment (estimated IQ score < 70).
- Changes in psychotropic medication in the 2 months prior to inclusion.

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:	Recruiting
Start date (anticipated):	01-12-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	07-09-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	19-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL57984.058.16