Effectiveness of the (POPP) treatment program in sexually abused preschool girls: a randomized controlled trial

No registrations found.

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

Summary

ID

NL-OMON20992

Source
Nationaal Trial Register

Brief title
POPP treatment for sexually abused preschool girls

Health condition

PTSD symptoms

Sponsors and support

Primary sponsor: GGZ Oost Brabant
Source(s) of monetary or material Support: GGZ Oost Brabant

Intervention

Outcome measures

Primary outcome

PTSD symptoms from baseline to post-intervention. The change in PTSD symptoms between the experimental and control group is compared at post-intervention.

Secondary outcome

Secondary outcomes are: Anxiety, Depression, Anger/Aggression, Dissociation, Sexual Concerns and General behavioral problems

Study description

Background summary

The main objectives of the present study are: assessing the effectiveness of the POPP-treatment program in girls aged 3-6 years with posttraumatic stress reactions following sexual abuse

Study objective

POPP treatment will lead to more PTSD symptom reduction compared to wait list.

Study design

The assessments will be conducted at baseline (T1), three months later at post-intervention (post-immediate POPP treatment, or at the end of waiting list: T2), and six months later (follow-up of immediate POPP treatment or post-treatment in the waiting list condition: T3)

Intervention

The POPP treatment program is based on Trauma Focused-Cognitive Behavior Therapy (TF-CBT) techniques, with a newly described central position for projection and healing play. Ten treatment sessions (for a maximum of 60 minutes each) are offered, along with parental guidance. Under the waiting list condition, the POPP treatment program starts after three months.

Contacts

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Eligibility criteria

Inclusion criteria

The criteria for inclusion are a) increased levels of PTSD symptoms, b) PTSD symptoms related to sexual abuse, and c) the child has reached the developmental level of symbolic play.

Exclusion criteria

Exclusion criteria are a) the absence of parental permission, b) severe psychiatric conditions that require an emergency response (suicidal intent, psychotic symptoms, or severe dissociations), c) the most recent episode of sexual abuse occurred more than 12 months before referral to the study, and d) lack of a long-term caretaker or severe family problems (lack of stability for the ongoing six months).

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):	01-07-2015
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-10-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41070
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5307
NTR-old	NTR5416
CCMO	NL50473.091.14
OMON	NL-OMON41070

Study results

Summary results

n/a