The effectiveness of the POPP-Treatment Program for sexually abused preschoolers: Healing Play as core element in Trauma-Focused Cognitive Behavioral Therapy.

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Objective: The main objective is to evaluate the effectiveness of the POPP-treatment program in reduction of severity of post-traumatic stress symptoms for sexually abused preschoolers. Secondary objectives are to evaluate the effectiveness of the...

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

Summary

ID

NL-OMON41070

Source
ToetsingOnline

Brief title
Effect of the POPP-treatment program for sexually abused preschoolers

Condition

- Anxiety disorders and symptoms

Synonym
Post-traumatic Stress Disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Healing play, Preschoolers, Sexual Abuse, Treatment

Outcome measures

Primary outcome

Posttraumatic stress disorder symptoms

Secondary outcome

secondary posttraumatic stress disorder symptoms: Anxiety, Depression,

Anger/Aggression, Dissociation, Sexual concerns;

general behavioral problems;

parental stress

Study description

Background summary

Rationale: Child Sexual Abuse (CSA) has large prevalence rates and can cause devastating short- and long-term effects on the overall development of children (Pereda et al, 2009, Cohen, Mannarino and Deblinger, 2012). Especially preschoolers are highly vulnerable in this respect (Kendall-Tacket, Meyer Williams and Finkelhor, 1993). The POPP (Power of Projection in Play) -treatment program is established in the field of clinical practice to help alleviate the negative consequences of sexual abuse for preschoolers. This study is the first randomized controlled trial (RCT) in which the effects of individual treatment on PTSD symptoms for sexually abused pre-schoolers are studied. We hypothesize that the POPP-treatment program will lead to decreases in PTSD and secondary symptoms in comparison with a waitlist condition.

Study objective

Objective: The main objective is to evaluate the effectiveness of the

POPP-treatment program in reduction of severity of post-traumatic stress symptoms for sexually abused preschoolers. Secondary objectives are to evaluate the effectiveness of the POPP-treatment program in reducing secondary symptoms: Anxiety, Depression, Anger/Aggression, Dissociation and Sexual Concerns; the evaluation of the effects of the POPP-treatment program on general behavioral problems and on parental stress/the enhancement of parental efficacy.
Another objective is to explore child- parents- or trauma factors which possibly relate to the effectiveness of the POPP-treatment program.

Study design

Randomized controlled trial with two conditions (immediate treatment vs waitlist).

Intervention

Intervention: The POPP-treatment program is based on Trauma Focused-CBT techniques (Cohen and Mannarino, 1996, Scheeringa et al, 2010), with a newly described central position for projection and healing play. A maximum of 10 treatment sessions (with a maximum of 60 minutes each) is offered, along with parental guidance. In the wait list condition, the POPP-treatment program starts after three months.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The potential value of the study is that we can offer sexually abused preschoolers a developmentally appropriate treatment program that combines TF-CBT with play, the language of children (Landreth, 2002), along with parental guidance.
We are of the opinion that the risks associated with participation can be considered negligible. The POPP-treatment program is based on solid grounds of past research findings on evidence-based treatments of PTSD, and has been used successfully in clinical practice for over ten years.
The burden is minimal; the POPP-treatment is a short-term treatment, the only extra investment for parents is time to fill in questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- the experience of sexual abuse
- girls, aged between 3 and 6;11 years
- PTSD symptoms at clinical level (on one or more PTSD-scales of TSCYC or according to DSM5)
- PTSD symptoms are related to sexual abuse
- consent has to be given by the subject's primary caretaker(s)
- the child must have reached the developmental level of symbolic play

Exclusion criteria

- severe psychiatric conditions that require an emergency response (suicidal intent, psychotic symptoms, severe dissociations)
- lack of a long-term caretaker or severe family problems (lack of stability for the ongoing 6 months)
- the most recent episode of sexual abuse occurred more than 12 months before referral to the study
- when parent(s) are the perpetrator(s), they will not participate in the parental guidance sessions.

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:	Pending
Start date (anticipated):	01-10-2014
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	09-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 20992

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50473.091.14
OMON	NL-OMON20992