KopOpOuders for PTSD: Randomized controlled trial of a blended care preventive parenting intervention for parents with PTSD.

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Main objective: to test the effectiveness of KOO-PTSD on parenting skills at the macro- and micro-level.Secondary objectives: to test the effectiveness of KOO-PTSD on perceived parenting competence, social support, parenting stress, child...

Ethical review	Approved WMO
Status	Completed
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON51894

Source
ToetsingOnline

Brief title
KopOpOuders-PTSD: Effectiveness of a course for parents with PTSD

Condition

- Psychiatric disorders NEC

Synonym
PTSD, trauma, traumatic stress

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Clinical Trial, Parenting, post-traumatic, Stress disorders

Outcome measures

Primary outcome

Primary study parameters are parenting behavior at the macro- and micro-level.

Secondary outcome

Secundary study parameters are sense of parenting competence, social support, parenting stress, psychosocial wellbeing of the child, and PTSD symptoms of the child.

The following variables are also measured: parental PTSD symptoms, trauma type/timing, psychosocial functioning, demographic information of the parent and child, number of completed modules/sessions, number of interactions with PTSD-specific online intervention content, satisfaction with the intervention, sleep quality, situational context, and distress level.

Study description

Background summary

Children of parents with post-traumatic stress disorder (PTSD) are at increased risk of mental health problems, such as depression, anxiety and hyperactivity. They are also more likely than children of healthy parents to be exposed to potential trauma, especially in the family setting (e.g., child maltreatment). Parents with PTSD often experience difficulties in their parenting role (e.g., deficits in effective parenting, sense of parenting incompetence, lack of social support). Research in other mental disorders shows that preventively supporting parents with mental illness in their parenting role decreases mental

health problems in children. As of yet, no preventive intervention specifically aimed at parents with PTSD exist. We will therefore adapt an existing preventive online course for parents with mental illness, *KopOpOuders zelfhulp*, into a blended care intervention for parents with PTSD: *KopOpOuders for PTSD* (KOO-PTSD).

Study objective

Main objective: to test the effectiveness of KOO-PTSD on parenting skills at the macro- and micro-level.

Secondary objectives: to test the effectiveness of KOO-PTSD on perceived parenting competence, social support, parenting stress, child psychological wellbeing, and child PTSD symptoms; to test whether intervention effects are moderated by baseline PTSD symptoms; and whether patterns can be detected in fluctuations of PTSD symptoms and hostile-coercive/supportive-engaged parenting throughout the day and week.

Study design

The study uses a single-blind randomized controlled trial design with three measurement points (pretest, posttest, and follow-up). Data are collected through self-report questionnaires and, for participants who agree to this, with ecological momentary assessment (EMA) using a smartphone app.

Intervention

The intervention group receives KOO-PTSD, consisting of 5 online modules and 3 face-to-face sessions, in addition to treatment as usual. The control group does not receive intervention apart from treatment as usual, but can access the online modules of KOO-PTSD after participation.

Study burden and risks

Participants are asked to meet three times with a researcher (online or in person) to complete questionnaires. Participants will also be asked if they want to participate in the EMA component. This is optional. The EMA component comprises the completion of three brief EMA assessments per day during a week each after pretest and posttest (42 assessments in total). Participants in the intervention condition complete eight sessions, five online and five face-to-face. The total estimated time investment for the intervention group is 12.3 hours (no EMA)/ 15 hours (EMA), and for the control group 2.7 hours (no EMA) / 5.5 hours (EMA). Participation may result in some psychological discomfort (e.g. some questions may be experienced as confronting), but no medical or physical risk is associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Has current DSM-5 diagnosis of PTSD;
• Is receiving PTSD treatment of at least three sessions at one of the following Arkin departments: Sinai Centrum, Jellinek, Punt P, NPI, or Arkin BasisGGZ;
• Has parenting responsibilities for at least one child aged 4-17 (biological or legal relationship not required);

Exclusion criteria

• Has urgent care needs or (imminent) crisis (e.g. current psychosis, substance detoxification, active suicidality);
• Is not in contact with children (e.g. due to out of home placement)

• Is receiving another form of parenting intervention during the participation period;
• Severe psychological problems are present in children (diagnosis of oppositional-defiant disorder, conduct disorder, psychotic spectrum disorder or personality disorder);
• Inability to participate in the intervention and/or assessments (e.g., because of mental disability (IQ < 75) illiteracy, or insufficient mastery of the Dutch language).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-06-2022
Enrollment:	142
Type:	Actual

Ethics review

Approved WMO Date:	16-12-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-03-2023
Application type:	Amendment
Review commission:	METC NedMec

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
ClinicalTrials.gov	NCT05237999
CCMO	NL78891.041.21