

Study on the effect of support groups for children, aged between 8 and 12 years, of parents with mental disorder or substance use disorder.

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It will be studied whether the support groups for children (8-12 year-olds) of parents with a diagnosed mental disorder and/or substance use disorder are effective in decreasing behavioural and emotional problems, strengthening competence and social...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON30785

Source

ToetsingOnline

Brief title

Effectstudy on the "KOPP" intervention (aged 8-12 years)

Condition

- Psychiatric and behavioural symptoms NEC
- Family issues

Synonym

"psychosocial problems" or "consequences of the parental disorder for the child"

Research involving

Human

Sponsors and support

Primary sponsor: Katholieke Universiteit Nijmegen

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: "Children of Impaired Parents", Intervention, Prevention, Randomized Control Trial

Outcome measures

Primary outcome

The primary outcome measures of the study are behavioural and emotional problems of the child and the emotional competency of the child.

Secondary outcome

The secondary outcome measures of the study are social functioning of the child and family functioning. Some factors will be studied exploratively, that might influence the effectiveness of the intervention: i.e. parental diagnosis, chronicity and severity of parental problems, parental competence and ethnical background.

Study description

Background summary

Over one third of the children of parents with a mental disorder (abbreviated in Dutch as *KOPP*) or children of parents with a substance use disorder (*KVO* in Dutch) develops serious and long-lasting problems themselves. Early in life, these children run a higher risk for abuse and neglect, depression, eating disorders, behavioural and academic problems. Later in lifetime, they are at higher risk for depression, anxiety disorders, substance abuse, eating problems and personality disorders. In the Netherlands, a coherent package of preventive interventions has been developed for *KOPP* children and in the meantime as well for children of parents with a substance abuse disorder. In this study, the effect of one of the longest running interventions will be tested, namely the preventive support-group for children, aged between 8 and 12 years, of

parents with mental and and/or substance abuse problems. The effect will be assessed on four variables: presence of psychosocial, behavioural and emotional problems, competency, social functioning of the child, and family functioning.

Study objective

It will be studied whether the support groups for children (8-12 year-olds) of parents with a diagnosed mental disorder and/or substance use disorder are effective in decreasing behavioural and emotional problems, strengthening competence and social functioning of the child and improving family functioning.

Study design

Children who participate in the group are compared to children who are on a waiting list for the group. To avoid a control condition in which participants are deprived of support, a randomized waiting list design is chosen for this study, in which all children can participate ultimately.

Intervention

The intervention is described in a standardized protocol (manual), which has been developed and standardized by several regional Mental Health Care services in collaboration with the Trimbos-instituut. Children participate in a group, which runs parallel to two group-sessions for parents. During eight sessions, children receive information about the problems of their parents, social support is offered as well as a training to learn strategies to enhance their competency (i.e. how to cope with the problems of their parents). Parallel to the group there are two parental meetings, one halfway through and one at the end. The parental meetings target to inform parents about the aim and content of the intervention for the children, improve understanding and involvement with the child's situation, offer parenting advices and information on the outcomes of the intervention.

Children who are on the waiting list (control condition) will receive three sessions of leisure time activities. The parents receive in the control conditions no additional activities.

Study burden and risks

It is expected that participation in this intervention will result in health benefits for the children. When effectiveness is demonstrated the intervention can be implemented more broadly and reach a larger proportion of the target population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

Children between the ages of 8 and 12 (12 included), who have at least one parent with a diagnosed mental disorder or substance use disorder (DSM-IV).

Parents with a diagnosed DSM-IV mental disorder (including: depression, anxiety disorders, bipolar disorder, schizofrenia or other psychotic disorder and personality disorder) or substance use disorder.

The parental mental disorder should have been diagnosed in a standardized interview by a mental health professional, during the last year.

Exclusion criteria

Children and parents who are not able to write and speak in Dutch.
Children who already receive or did receive psychological treatment for their mental problems (since this study is focused on the outcomes of a primary preventive intervention).
Children who are not in primary school anymore during post-test or follow-up test (the transition between primary and secondary school can cause too much variance in child outcome).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	228
Type:	Actual

Ethics review

Approved WMO	
Date:	05-09-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL13231.091.06