

# Effectiveness of preventive support groups for children (aged 8-12) of mentally ill or addicted parents

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<b>Registration date</b> 18/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/09/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Children who grow up with a mentally ill or addicted parent are at high risk to develop problems themselves during their life. They are for instance at risk for various psychiatric disorders, such as depression and anxiety, but also for other problems like poor functioning in school and peer relations, suicide, and medical illnesses. The risk in these children is caused by a combination of inherited genes, biological processes caused by maternal stress during pregnancy, and environmental risk factors. With environmental risk factors we mean for instance problematic family functioning, a poor relationship between parent and child, and several child characteristics which make them more vulnerable for problems such as a low self-esteem. Since the environmental risk factors are malleable, over the years various preventive courses have been developed for these children to lower their risk and increase their strengths. In the Netherlands, nearly all mental health centres offer preventive support groups for the children of their adult patients. In the support groups, children meet, talk and play with other children of mentally ill or addicted parents. The groups aim to decrease the risk in these children by teaching them that other people that give them support. Children learn how they can ask for this social support, how to interact with their parent, how to cope with difficult situations, that they are not the only one with a mentally ill parent, and that they need not feel guilty or ashamed. This might lead to increases in self-esteem and feelings of social acceptance by peers. Although the support groups have been offered to the children for many years, until now, there is no information about whether the children who participate really learn the skills and have fewer problems afterwards. Therefore, this study will answer these questions.

### Who can participate?

Twenty Dutch mental health centers that offer support groups for children aged 8 to 12 years old participate in the study. Children who are enlisted for a support group in one of these centers can participate. The children need to have a parent who is diagnosed with a mental disorder or substance use disorder. The children themselves have to be aged between 8 and 12 years old.

What does the study involve?

The children will be randomly assigned to one of two groups. One group will immediately start with the support group intervention. The support group intervention consists of eight weekly 90-minute sessions, each with a unique theme. Each session starts with an evaluation of the last week and a group discussion and is closed with a homework assignment. Children receive information (psycho-education), discuss topics and practice skills by doing role plays, games, creative activities and multimedia. Between the fourth and fifth session of the group there is a meeting for parents, and parents are also involved in a final family talk. Three months after the last session children meet again in a come back session (booster session). All sessions are supervised by a prevention and a child mental health expert. The other group will be put on a waiting list for 6 months. In order to prevent children from dropping out, the children on the waiting list are offered three pleasant activities, such as paintballing or watching a movie. After 6 months, when the study is finished, the groups change (children who first did the support groups now undertake three pleasant activities, and vice versa). The two groups will be compared in terms of the four goals of the support groups and their emotional and behavioural problems. The goals and their problems will be assessed by questionnaires that will be filled out by themselves and one of their parents. The questionnaires should be completed before start of the group, afterwards (3 months later), and 6 months after the start to see whether the effects are maintained.

What are the possible benefits and risks of participating?

The possible benefits are a reduction in risk and an improvement in strengths of the children. There are no risks.

Where is the study run from?

The study is conducted by the Radboud University Nijmegen (Netherlands) in cooperation with the Dutch National Institute for Mental Health and Addiction (Trimbos Institute). Twenty mental health centers are participating: Centrum Maliebaan, Context, De Jutters, Dimence, GGNet, GGZ Breburg, GGZ Friesland, GGZ Nijmegen, GGZ Oost Brabant, Indigo, Mediant, Mentrum, Mondriaan, Novadic Kentron, Optiment, Prezens, Reinier van Arkel Groep, Riagg Maastricht, Riaggzuid, Tactus.

When is the study starting and how long is it expected to run for?

The study ran from October 2007 to June 2010.

Who is funding the study?

The study is funded by ZonMw, which is the Dutch Organization for Health Research and Development.

Who is the main contact?

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## Contact information

**Type(s)**

Scientific

**Contact name**

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**Contact details**

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

**Study information****Scientific Title**

A randomized controlled trial of a preventive support group intervention aimed at preventing problem development in children of parents with mental disorder or substance use disorder

**Study objectives**

We expected that after children participated in a support group, they would:

1. Seek more social support
2. Have less negative cognitions related to parental illness (guilt, shame, loneliness)
3. Have higher feelings of competence (self-worth & social acceptance)
4. Perceive a higher quality in the interaction with their ill parent
5. Have less emotional and behavioral problems compared to children who did not participate

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Dutch Medical Ethics Committee for Mental Health Centers (METiGG), 12 September 2007 ref: 7.106

**Study design**

Interventional multicentre randomized non blinded trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Mental health problems in children at risk

**Interventions**

Intervention (support groups)

The support groups comprise eight weekly sessions (1.5 hours) and a booster session after 2-3 months for children, one parent session, and a finishing family talk. All sessions are supervised by two trainers: a (child) mental health and a prevention expert.

Each session starts with an evaluation of the last week and a group discussion and is closed with a homework assignment. Other techniques that are used include role plays, games, psycho-education, and discussions about several topics introduced through creative activities or multimedia. Leisure activities are also an important part as for many children moments to be a child without worries are scarce. Detailed instructions and contents of all the sessions are described in a standardized manual. The theory and practice based manual was developed in 2001 by a collaboration between local prevention experts and the Dutch National Institute for Mental Health and Addiction (Trimbos Instituut), and is now used by all Dutch mental health centers.

Control (Six months waiting list with three leisure activities [parallel to the eight support group sessions])

Since the support groups are already offered for many years, it would have been unethical to deprive half of the children of the intervention. Hence, the control group participants received the support group intervention after six months when their participation in the study was finished. Moreover, while they were on the waiting list, these control group participants were offered three group-based leisure activities in order to reduce drop-out. The activities were organized by the mental health centers and were guided by one or two mental health or prevention experts or students. All activity sessions constituted of a group activity part, such as a game or a quest, and an individual activity part, like painting or baking cookies. Children were not stimulated to discuss their home situation. However, when a child started to talk about his /her ill parent, the group leader talked with the child separately from the other children.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Emotional and behavioral problems

Measured with the Strengths and Difficulties Questionnaire, filled out by the parent (SDQ) (total

problem scale) (0 = no problems, 40 = high problems, 14= Dutch clinical cut-off score) at baseline, after three months, and six months.

2. Child's negative cognitions measured with four self-developed questions regarding experiences of guilt, shame, and loneliness regarding the parental illness (mean score, justified with factor-analysis), filled out by the child (1 = low negative cognitions, 5 = high negative cognitions) at baseline, after three months, and six months.

3. Child's perceived social support

Measured with three self-developed questions about the number of people with whom the children: communicate about their own problems, communicate about their ill parent, and undertake leisure activities, filled out by the child (mean score, justified with factor-analysis) (0 = low social support, 14 = high social support) at baseline, after three months, and six months.

4. Child's perceived competence

Measured with two subscales of the Dutch version of the Self-Perception Profile for Children (SPPC): social acceptance and global self-worth (both scales: 6 = low perceived competence, 24 = high perceived competence) at baseline, after three months, and six months.

5. Parent-child interaction

Measured with the Dutch Parent Child Interaction Questionnaire (OKIV), filled out by the child (total score) (25 = low quality of parent child interaction, 125 = high quality of parent child interaction) at baseline, after three months, and six months.

### **Secondary outcome measures**

No secondary outcome measures

### **Overall study start date**

02/10/2007

### **Completion date**

14/06/2010

## **Eligibility**

### **Key inclusion criteria**

Children have at least one parent meeting the DSM-IV diagnostic criteria on Axis I or Axis II or the ICD-10 criteria for a mental disorder or substance use disorder

### **Participant type(s)**

Patient

### **Age group**

Child

### **Sex**

Both

### **Target number of participants**

228 participants in total (114 per arm)

### **Key exclusion criteria**

1. Children with a current psychiatric diagnosis
2. Children who received psychological treatment during the last year
3. Children who had already participated in a support group

**Date of first enrolment**

02/10/2007

**Date of final enrolment**

14/06/2010

## Locations

**Countries of recruitment**

Netherlands

**Study participating centre****Radboud University**

Nijmegen

Netherlands

6500 HE

## Sponsor information

**Organisation**

The Netherlands Organisation for Health Research and Development [ZonMw] (Netherlands)

**Sponsor details**

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Postbox 93245

Den Haag

Netherlands

2509 AE

**Sponsor type**

Research organisation

**Website**

<http://www.zonmw.nl/en/>

**ROR**

<https://ror.org/01yaj9a77>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Dutch Organization for Health Research and Development (ZonMw) ref: 62300034

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2014		Yes	No