ISRCTN48032451 https://doi.org/10.1186/ISRCTN48032451

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

Submission date
09/12/2011

Recruitment status
No longer recruiting

Registration date
18/01/2012

Overall study status
Completed

Last Edited
20/09/2018

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Ms Floor van Santvoort
f.vansantvoort@psych.ru.nl

Contact information

Type(s)
Scientific

Contact name
Ms Floor van Santvoort

Contact details
Radboud University
Department of Clinical Psychology
PO Box 9104
Nijmegen
Netherlands
6500 HE
+31 2436 12748
f.vansantvoort@psych.ru.nl

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 Institut), 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
Laan van Nieuw Oost Indië 334
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?
Results article	results	01/06/2014		Yes	No