ISRCTN52310507 https://doi.org/10.1186/ISRCTN52310507

Evaluation of support group interventions for children

Submission date	Recruitment status	[_] Prospectively registered
21/05/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/09/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2015	Mental and Behavioural Disorders	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

In the last few decades, support groups have become popular for offering preventive methods for children at risk in Sweden. These methods are used for children in families with a variety of parental problems such as alcohol/drug abuse, mental illness, family violence, imprisonment or divorce conflicts. These children are known to be a high-risk group for severe mental health and /or social problems. Support groups are available in a majority of Swedish municipalities and are run mainly by social or public health services, and by non-governmental organizations (NGOs). The number of children and youths who are attending support groups has been estimated to about 2500 a year, but there are no figures of the total number of children who attend support groups. The main purpose of the support group is to strengthen the children's coping behaviour, to improve their mental health and to prevent a negative psycho-social development. Although the method is widespread, research has so far been limited. Previous studies looked at children's experiences and satisfaction with the support group. There is a shortage of studies on how well these methods work and therefore, there is no evidence whether these methods used in Sweden have an effect. The aim of this study is to find out whether support group methods have an effect regarding children's global mental health, coping behaviour, rated quality of life and self-perception.

Who can participate?

The study is open to children aged 7-13 years, in families where at least one of the parents (or other caregiver) has problems related to alcohol/drug abuse, mental illness, family violence, divorce problems or a parent in prison.

What does the study involve?

Participants are randomly allocated to either an intervention group, who will receive a support group intervention, or a waiting list control group, who will receive treatment as usual (TAU). The assessment consists of questionnaires that are to be filled in by the participants at the start of the study. The intervention group participants will then be followed up four and twelve months after. The control group participants will be followed up once - four months from the start of the study.

What are the possible benefits and risks of participating?
Having in mind the overall aim of the support group intervention, it is anticipated that participation may result in benefits such as improved mental health, coping behaviour and quality of life. Some participants may feel discomfort as they are asked to reflect over their own situation, behaviour and relations. However, it is stressed that the study is anonymous and strictly voluntary and the participants can choose to leave the study at any time.

Where is the study run from?
Recruitment is carried out through contacts with all organisers of support groups in the Stockholm area and through the BGS website (www.barngruppstudien.se).

When is the study starting and how long is it expected to run for?
February 2010 to January 2014.

Who is funding the study?
The study has been funded by grants from the Swedish National Institute of Public Health and the City of Stockholm, Sweden.

Who is the main contact?
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Study website
http://www.barngruppstudien.se/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HFÅ 2011/575

Study information

Scientific Title
Effects of support group interventions on children in families with parental problems related to alcohol, drug abuse, mental illness, family violence, imprisonment or a complicated divorce situation

Acronym
BGS (Barngruppstudien)

Study objectives
The intervention group in comparison to the control group, representing treatment-as-usual will:
1. improve their mental health
2. improve their coping behavior
3. improve their expected quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board, Stockholm, 08/04/2010 ref: 2010/5:4 and 16/12/2010, ref: 2010 /5:12

Study design
Single-centred parallel-group unblinded controlled intervention study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

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
Affected children in families with parental problems

Interventions
Intervention: Support group intervention for children living in families with parental problems. Waiting list control group, representing treatment-as-usual (TAU), are offered a support group intervention after the trial period. No other intervention is offered to them.
The support group interventions are derived from the manual-based CAP (Children are People Too) intervention, consisting of:
1. 8 - 12 thematic group sessions (each between 90 -120 min) discussing different aspects of parental problems in the family
2. Each session contains lectures related to the specific problem that the group aims at
3. Each session contains various games, role plays and practises related to family problem and coping behaviour

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Study assessments take place at baseline, at 4 and 12 months following baseline.
1. Mental health is measured using the Strength and Difficulties Questionnaire to the child and the parent (SDQ-P and SDQ-S 11-16)
2. Coping behaviour is measured using the Kids Coping Test questionnaire (four-point Likert scales) to the child.
3. Overall life satisfaction will be measured by asking about the participants' past, present and future rating of his/her life on a ten-point 'Ladder of life', representing life status from 'worst' to 'best' possible life imaginable using a one year time frame
4. Self perception is measured using the Swedish Scale 'Jag tycker jag är' (I think I am) questionnaire. 'Jag Tycker Jag Är L' is a 32-item, two-point Likert scale for children (7-9 years). 'Jag Tycker Jag Är M-H' is a 72-item, four-point Likert scale for children (10-15 years).
4. Parent/other adult also answers the Swedish Scale Family Climate (Familjeklimat)

Secondary outcome measures
Program adherence will be measured using a questionnaire to group leaders listing all activities during the group sessions

Overall study start date
10/02/2010

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Child should be 7-13 years old
2. Child should be from family with at least one of the parents has problems such as addiction to alcohol/drugs, mental illness, family violence, divorce or imprisonment
3. Informed consent from custodian/custodians

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
116

Key exclusion criteria
1. Previous support group experience
2. Parents refused to give consent

Date of first enrolment
10/02/2010

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Stockholm Centre for Psychiatric Research and Education
Stockholm
Sweden
10231

Sponsor information

Organisation
The Swedish National Institute of Public Health (FHI) (Sweden)

Sponsor details

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Östersund
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Sponsor type
Government

Website
http://www.fhi.se

ROR
https://ror.org/05x4m5564

Funder(s)

Funder type
Government

Funder Name
Preventionscentrum Stockholm (Sweden) DNR: 3.2-0670/2009

Funder Name
Swedish National Institute of Public Health (Sweden) ref: HFÅ 2010/54 ; HFÅ 2011/575

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?
Protocol article	protocol	24/01/2014		Yes	No