

Project Trampoline - designing and evaluating a modular prevention program for children from substance-abusing families

Submission date 21/06/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 13/09/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/04/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Children from substance (drug) abusing families have a high risk of developing psychological or substance related disorders in adolescence or early adulthood. However, in Germany there are few prevention programs aimed at reducing psychological stress for these children, and to date none have been scientifically tested. The aim of this study is to develop and test a modular group program called Trampoline for 8- to 12-year-old children from substance-abusing families in Germany.

Who can participate?

Children aged 8-12 who have at least one drug-abusing parent

What does the study involve?

Participants are randomly allocated to receive either the Trampoline program or treatment as usual.

The Trampoline program consists of nine modules (each 90 minutes) including exercises, role play, relaxation techniques, discussions and education. Before and after the program and 6 months later all participating children are assessed using questionnaires about current parental substance use, stress level and coping strategies, family relationship quality, self-worth, self-efficacy and satisfaction with the intervention. The parents also report on several of these areas and on parenting style and child behaviour.

What are the possible benefits and risks of participating?

The results of this study will provide fundamental information on the effectiveness of a structured group prevention program for German children from substance abusing families, helping to create a more effective system of help for this high-risk group. There are no physical or psychological risks for participants.

Where is the study run from?

German Center for Addiction Research in Childhood and Adolescence (Deutsches Zentrum für Suchtfragen des Kindes- und Jugendalters [DZSKJ]) (Germany)

When is the study starting and how long is it expected to run for?
October 2008 to March 2012

Who is funding the study?
Federal Ministry of Health (Germany)

Who is the main contact?
Dr Annika Wiedow
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Study website
<http://www.projekt-trampolin.de>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IIA5-2508DSM211

Study information

Scientific Title
Project Trampoline - designing and evaluating a modular prevention program for children from substance-abusing families: a longitudinal prospective randomized controlled multi centre study

Acronym
Trampoline

Study objectives

1. Children of substance abusing parents who have participated in the trampoline program (intervention group), in contrast to children who have participated in the attending playgroup (control group 1), have a significant improvement in their coping strategies immediately after the intervention (time t2), general and in relation to parental substance abuse.
 2. Children of substance abusing parents, who participated in the trampoline program (intervention group), in contrast to children who have participated in the play group (control group 1), also 6 months after the intervention (time t3) is still significant improvements in their chosen coping strategies, general and in terms of parental addiction.
- The following hypotheses are not formulated for practical reasons for each relevant survey period, a separate hypothesis, but the particular hypothesis divided into parts a) time t 2 and b) at time t3.
3. Children of substance abusing parents, who participated in the trampoline program (intervention group), in contrast to children who have, references to the play groups (control group 1), a) direct (time t2) and b) 6 months after the intervention (time t3), have a significant improvement in their psychological distress.
 4. Children of substance abusing parents, who participated in the trampoline program (intervention group), in contrast to children who have participated in the play group (control group 1), a) direct (time t2) and b) 6 months after the intervention (time t3), a significant improvement in their level of knowledge on the effects of alcohol and other drugs, the clinical picture of "addiction" and the effects of addiction to other family members.
 5. Children of substance abusing parents, who participated in the trampoline program (intervention group), in contrast to children who have participated in the play group (control group 1), a) direct (time t2) and b) 6 months after the intervention (time t3), have a significant improvement in their self-concept and their self-worth.
 6. Children of substance abusing parents, who participated in the trampoline program (intervention group), in contrast to children who have participated in the play group (control group 1), a) direct (time t2) and b) 6 months after the intervention (time t3), have a significant improvement in their self-efficacy.
 7. Children of substance abusing parents, who participated in the trampoline program (intervention group), in contrast to children who have participated in the play group (control group 1), a) direct (time t2) and b) 6 months after the intervention (time t3), have a significant improvement in their health-related quality of life, that mean their subjective health and well-being.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical Association of Hamburg, 19/11/2009

Study design

Longitudinal randomized controlled cross-sectional study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Counseling program for children of substance abusing families

Interventions

Intervention group, participants N = 120, group intervention with 9 modules (each 90 min), relevant addiction-related content

Control group, participants N = 120, play group with 9 modules (each 90 min), addiction-unrelated content

1. Trampoline is a modular, manualized group intervention designed for 6-8 participants, aged 8-12 years. Special attention is paid to a recurring structure of the sessions, which children often lack in substance-affected homes.

1.1. 9 modules with 90 min., 2 parents sessions

1.2. Relevant addiction-related content

1.3. Interactive, age- and gender-sensitive setup

1.4. Exercises, roles-play, relaxation techniques, discussions, education

Modules:

1. Create trust and positive group atmosphere

2. Self-worth: how I feel about myself

3. Alcohol and / or drug problems in my family

4. What I need to know about drugs and addiction

5. Handling difficult emotions

6. Self-efficacy: What I can do to solve problems

7. Learning new behaviours in my family

8. What I can do to find help and support

9. A positive goodbye

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Children:

1. Learn effective coping strategies (dealing with emotions, problem-solving strategies in the family, help-seeking behavior).

2. Reduction of mental stress by solving the taboo topic addiction

4. Increase the level of knowledge of the children on the effects of drugs and the effect of addiction on the person and their family

5. Increase self-esteem / building a positive self-concept

6. Increase self-efficacy

All data (sociodemographic details, outcome variables) are measured by questionnaires, one for children and one for their parents. Three points of measurement exist: pre treatment, post treatment and six-months-follow-up

Secondary outcome measures

Adults

- 1.Strengthening the parents regarding their confidence in parenting
- 2.Promoting parenting skills
- 3.Greater awareness of the impact of parental addiction on children

All data (sociodemographic details, outcome variables) are measured by questionnaires, one for children and one for their parents. Three points of measurement exist: pre treatment, post treatment and six-months-follow-up

Overall study start date

01/10/2008

Completion date

31/03/2012

Eligibility

Key inclusion criteria

1. Age range from 8-12 years
2. Current or recent past substance abuse or dependence at least one parent, a positive diagnosis is crucial in the last year
3. The children have in the past two years lived together with the (step) parent, fell ill at least half a year, respectively, have had regular visitation or contact with on weekends - in the case of the parents living apart.
4. Written consent of parents and children to participate in the study
5. No diagnosis or no suspicion of Fetal Alcohol Spectrum Disorder (Fetal Alcohol Spectrum Disorders = FASD) in children

Participant type(s)

Other

Age group

Child

Lower age limit

8 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

240

Key exclusion criteria

1. Relevant treatment in the last 6 months prior to study at the project site or at another institution (relevant to the objectives of this study treatment, e.g. when the child was explicitly told about the impact of parental addiction, counseling or support is provided).

1.1. Not excluded are children participating in group or individual programs unrelated to the study aims, e.g., homework assistance, occupational therapy etc. Children who participate in any kind of programs/groups targeting the substance abuse of the parents have to be excluded

1.2. Has the child attended in the past because of the impact of parental addiction on a specific measure, but this is already longer than 6 months back, the child may participate in the project, since no treatment effects of the measure can be accepted.

Date of first enrolment

01/10/2008

Date of final enrolment

31/03/2012

Locations

Countries of recruitment

Germany

Study participating centre

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Sponsor information

Organisation

German Center for Addiction Research in Childhood and Adolescence (DZSKJ) (Germany)

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Sponsor type

Hospital/treatment centre

Website

<http://www.uke.de/zentren/suchtfragen-kinder-jugend/index.php>

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Gesundheit (ref: IIA5-2508DSM211)

Alternative Name(s)

Federal Ministry of Health, Germany, Federal Ministry of Health, BMG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

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	22/03/2012		Yes	No