

# Evaluation of the German adaptation of the US-American family based prevention program against substance abuse, "Strengthening Families Program 10-14"

<b>Submission date</b> 07/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/05/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/09/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.familien-staerken.info>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

01EL0810

# Study information

## Scientific Title

Randomized controlled multicenter evaluation of the German adaptation of the US-American family based prevention program against substance abuse "Strengthening Families Program 10-14"

## Study objectives

1. Adolescents who attend the adapted German version of "Strengthening Families Program 10-14" will significantly later begin the consumption of tobacco, alcohol and cannabis.
2. On average, adolescents in the intervention group will consume less of these substances than the controls group
3. Adolescents from the intervention group will manifest less behavioural problems in school and at home than controls

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Medical Association of Hamburg, Germany

## Study design

Controlled randomized longitudinal and 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 below to request a patient information sheet

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

Substance abuse and behavioural disorders in adolescents

## Interventions

Intervention:

1. The German version of the Strengthening Families Program 10-14, now called Familien

stärken consists of 11 training sessions which last two hours each

2. The first 7 sessions are held weekly, followed by a pause of 2-3 months.

3. Then, another 4 booster sessions are held weekly

4. Up to nine families with their children aged 11-13 take part in the intervention

5. The groups are led by 3 facilitators who have a degree in social education

6. During the first hour of the training, parents and adolescents are separated and attend individual groups

7. In the second hour, families are reunited for the family session

8. The program aims at improving adolescents self-efficacy, coping with stress and with peer pressure

9. Parents are encouraged to reflect their education style, to develop a more consistent form of parenting and to express positive affect more openly

10. Dysfunctional communication patterns within the family are addressed and family cohesiveness is strengthened

Control:

1. Parents gather for a single session which lasts 2 ½ hours

2. Here, parents learn about adolescents and substance abuse and about ways to improve their parenting styles

Pre and post intervention assessments and follow-ups after 6, 12, and 18 months

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

1. Adolescents substance consumption

2. Adolescents mental health status

3. Adolescents self-efficacy

4. Adolescents problem behaviour

5. Parenting style

6. Level of family functioning

7. Measuring points for both arms are at baseline, post intervention (after the booster sessions), as well as 6 and 18 months after the intervention ended (follow ups)

### **Secondary outcome measures**

1. Parents mental health status

2. Parents self-efficacy

3. Parents' self-efficacy in parenting

### **Overall study start date**

01/03/2010

### **Completion date**

31/03/2013

## **Eligibility**

**Key inclusion criteria**

1. Age range from 11-13
2. Living in an economically deprived area of a city
3. The capability to attend group programs

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

11 Years

**Upper age limit**

13 Years

**Sex**

Both

**Target number of participants**

288

**Key exclusion criteria**

1. A diagnosed substance abuse disorder
2. Currently participating or having participated in the past six months in another comparable prevention program

**Date of first enrolment**

01/03/2010

**Date of final enrolment**

31/03/2013

**Locations****Countries of recruitment**

Germany

**Study participating centre**

Martinistr. 52

Hamburg

Germany

20246

**Sponsor information**

## Organisation

German Federal Ministry of Education and Research [Bundesministerium für Bildung und Forschung (BMBF)] (Germany)

## Sponsor details

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## Sponsor type

Government

## ROR

<https://ror.org/04pz7b180>

## Funder(s)

### Funder type

Government

### Funder Name

German Federal Ministry of Education and Research (BMBF), ref: 01EL0810.

## 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="#">Protocol article</a>	protocol	27/01/2014		Yes	No

