

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

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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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)

Key secondary outcome(s)

1. Parents mental health status
2. Parents self-efficacy
3. Parents' self-efficacy in parenting

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

11 years

Upper age limit

13 years

Sex

All

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)

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

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	27/01/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes