

"Be Independent (Eigenständig werden)" prevention trial: a school-based substance use prevention programme based on the Social Influence Approach

Submission date 06/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/12/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

108374

Study information

Scientific Title

A school-based substance use prevention programme based on the Social Influence Approach: a prospective cluster randomised controlled trial

Study objectives

Participation in the prevention programme "Eigenständig werden" leads to higher social and personal competencies, lower rates of substance use and initiation, better knowledge on substance use, lower susceptibility to smoking and alcohol and more negative attitudes towards substances.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Board of Medical Faculty of Christian Albrechts University Kiel, Germany, approved on the 23rd April 2010 (ref: D419/10)

Study design

Prospective cluster randomised controlled trial

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

Tobacco and alcohol dependence

Interventions

"Eigenständig werden" (Becoming independent) is a school-based life skill programme with substance specific units and information of parents. Trained teachers implement 9 units school year. In the control group, classes receive treatment as usual (normal school lessons).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Life skills, social and interpersonal competencies
2. Smoking and alcohol use behaviour (lifetime, current) and intentions

These will be measured at baseline, post-test 1 (end of grade 5), post-test 2 (end of grade 6), 6 and 18 months follow-up.

Secondary outcome measures

1. Knowledge on smoking and alcohol
2. Attitudes on smoking and alcohol

These will be measured at baseline, post-test 1 (end of grade 5), post-test 2 (end of grade 6), 6 and 18 months follow-up.

Overall study start date

01/05/2010

Completion date

15/01/2014

Eligibility

Key inclusion criteria

1. Students of public schools
2. Aged between 10 and 12 years (grade 5 to 6), either sex

Participant type(s)

Patient

Age group

Child

Lower age limit

10 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

3160 students (in 158 classes)

Total final enrolment

3444

Key exclusion criteria

1. Students of schools with special pedagogic needs
2. Missing consent of school
3. Missing parental consent

Date of first enrolment

01/05/2010

Date of final enrolment

15/01/2014

Locations**Countries of recruitment**

Germany

Study participating centre

IFT-Nord

Kiel

Germany

24114

Sponsor information**Organisation**

German Cancer Aid (Deutsche Krebshilfe e.V.) (Germany)

Sponsor details

Buschstr. 32

Bonn

Germany

53113

Sponsor type

Charity

Website

<http://www.krebshilfe.de>

ROR

<https://ror.org/01wxdd722>

Funder(s)

Funder type

Charity

Funder Name

German Cancer Aid (Deutsche Krebshilfe e.V.) (Germany) (ref: 108374)

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	6-month follow-up results	21/01/2014	29/12/2020	Yes	No
Results article	results	01/01/2011	29/12/2020	Yes	No