

# Effectiveness of the "Smoke-Free Class competition" in delaying the onset of smoking in adolescence: a cluster-randomised controlled trial (Germany)

<b>Submission date</b> 11/04/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/10/2012	<b>Condition category</b> 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**  
N/A

# Study information

## Scientific Title

### Study objectives

"Smoke-Free Class competition" (SFC) shows a preventive effect on knowledge on smoking, attitudes towards smoking, and smoking behaviour.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved by state administration department of Saxony-Anhalt (Landesverwaltungsamt Sachsen-Anhalt) on the 31st August 2006 (ref: Reg.-Nr. 504-50/06).

### 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

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

Smoking prevention

### Interventions

Since the intervention was planned to take place at the class level, schools were chosen as the unit of randomisation. Experimental schools would provide the SFC, while control schools would provide normal lessons.

Intervention - Be Smart Don't Start (the German version of the Smoke-Free Class Competition): Each participating class has to decide if they want to be a Smoke-free Class for a six month period from fall to spring. Classes monitor their (non-)smoking behaviour and report it to the teacher regularly. Classes, in which pupils refrain from smoking for this period of time participate in a prize draw.

Control - treatment as usual:  
Normal lessons.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. Knowledge on smoking consequences
2. Attitudes towards smoking
3. Intention to use tobacco
4. Smoking status

These will be measured at end of treatment, and at 12 and 18 months follow-up.

**Secondary outcome measures**

1. Class climate
2. Bullying

These will be measured at end of treatment, and at 12 and 18 months follow-up.

**Overall study start date**

15/10/2006

**Completion date**

01/03/2009

**Eligibility****Key inclusion criteria**

1. Students of public schools
2. Age between 11 and 15 (grades 6 to 8)
3. No prior participation at Be Smart Don't Start
4. No shutdown of school planned in near future

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

11 Years

**Upper age limit**

15 Years

**Sex**

Both

**Target number of participants**

84 schools/206 classes/3,497 students (already recruited)

**Key exclusion criteria**

1. Students of schools with special pedagogic needs
2. Students from schools currently conducting structured interventions against substance use
3. Missing parental consent

**Date of first enrolment**

15/10/2006

**Date of final enrolment**

01/03/2009

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

Germany

**Study participating centre**

Düsternbrooker Weg 2

Kiel

Germany

24105

**Sponsor information****Organisation**

German Cancer Aid (Deutsche Krebshilfe) (Germany)

**Sponsor details**

Buschstr. 32

Bonn

Germany

53113

ek@krebshilfe.de

**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) (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?
<a href="#">Results article</a>	results	01/03/2010		Yes	No
<a href="#">Results article</a>	results	01/04/2012		Yes	No
<a href="#">Results article</a>	results	01/04/2012		Yes	No