

Effectiveness of the "Smoke-Free Class Competition" (SFC) in delaying the onset of smoking in Polish students: a cluster-randomized controlled trial

Submission date 18/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/01/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/05/2008	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

Contact name

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Contact details

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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

SFC shows a preventive effect on knowledge, attitudes and smoking behaviour

Ethics approval required

Old ethics approval format

Ethics approval(s)

Bioethics Commission of the University of Medical Sciences in Poznan, Poland. Date of approval: 15 May 2008 (ref: 511/08)

Study design

Prospective, cluster-randomized, controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Smoking prevention

Interventions

Participating schools will be randomised to the intervention and control groups.

Intervention group: "Smoke-Free Class Competition" ("Współzawodnictwo Klasa Wolna od Dymu")

Control group: Treatment as usual

Description of the intervention: 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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The following will be assessed by questionnaires at the end of intervention and at 12- and 18-month follow-up:

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

Secondary outcome measures

The following will be assessed by questionnaires at the end of intervention and at 12- and 18-month follow-up:

1. Class climate
2. Bullying

Overall study start date

15/10/2007

Completion date

31/12/2009

Eligibility**Key inclusion criteria**

1. Students of public schools
2. Age between 10-13 years old (10 year on the beginning of the study, 4th grade)
3. Written consent of parents

Participant type(s)

Patient

Age group

Child

Lower age limit

10 Years

Upper age limit

13 Years

Sex

Both

Target number of participants

81 schools / 142 classes / 2,940 students

Key exclusion criteria

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

Date of first enrolment

15/10/2007

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Germany

Poland

Study participating centre

Institute for Therapy and Health Research (IFT- Nord)

Kiel

Germany

24105

Sponsor information

Organisation

European Commission

Sponsor details

DG Health and Consumer Protection

Brussels

Belgium

1049

Sponsor type

Other

Website

http://ec.europa.eu/index_en.htm

ROR

<https://ror.org/00k4n6c32>

Funder(s)

Funder type

Other

Funder Name

European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκή Επιτροπή, Европейская комиссия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságrol, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

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