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Education Against Tobacco (EAT): a quasi-experimental prospective evaluation of the largest medical-student-delivered smoking prevention programme for secondary schools in Germany

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ABSTRACT

Objectives: To evaluate the largest medical-student-delivered tobacco prevention programme for secondary schools for its effectiveness to reduce the smoking prevalence among 10-15 year olds in Germany at half year follow-up.

Setting: We used a prospective quasi-experimental study design with two measurements at baseline (t1) and 6 months post-intervention (t2) to investigate an intervention in 8 German secondary schools.The participants were split into intervention- and control classes in the same schools and grades.

Participants: A total of 1,474 eligible participants of both genders at the age of 11-15 years were involved within the survey at baseline of which 1,200 completed the questionnaire at six months follow-up. The schools participated voruntarily. The inclusion criteria were age (10-15 years), grade (6-8) and school type (regular secondary schools).

Intervention: Two 60-minute school-based modules delivered by medical students.

Primary and secondary outcome measures: The primary end point was the prevalence of smokers and non-smokers in the two study arms at 6 months after the intervention. The percentage of former smokers and new smokers in the two groups were studied as secondary outcome measures.

Results: We report a significant effect ($p<0.01$) for the defined primary endpoint. In the control group, the percentage of students who claimed to be smokers doubled from 4.2% (t1) to 8.1% (t2), whereas it remained almost the same in the intervention group (7.1% (t1) to 7.4% (t2)). The chance of quitting smoking was almost six times higher in the intervention group (total of 67 smokers at t1; 27 (4.6%) quitted in the

intervention- and 7 (1.1%) in the control group; odds ratio: 5.63; 95% confidence interval: 1.74–18.24; p<0.01). However, no primary preventive effect was measured.

Conclusion: We report a significant secondary preventive effect at six months follow-up. Long-term evaluation of the programme will be the focus of future investigations.

Keywords: medical students, tobacco prevention, secondary schools, smoking cessation, adolescents, school-based prevention

Strengths and limitations of this study

- No medical-student-delivered school-based tobacco prevention programme has been evaluated for its preventive effect to date.
- It is imperative to sensitize prospective physicians to tobacco prevention.
- The quasi-experimental design of this study caused a selection bias due to the lack of randomization.
- As control classes were located in the same schools, cluster effects could not be excluded entirely.
- Our follow-up data was only collected six months after the intervention due to organisational reasons. Thus, we were not able to determine long-term effects.

Background

Smoking is the biggest external cause of non-contagious disease and is responsible for more deaths than obesity both globally and in high-income countries such as

Germany or the USA [1-3]. Smoking was responsible for almost 107,000 deaths in Germany in 2007 [3].

Most smokers start smoking in early adolescence [4, 5]. The 2011 European School Survey Project on Alcohol and Other Drugs report revealed that a higher percentage of 16-year-old pupils from Germany claimed to have smoked in the past 30 days (33%) than pupils from Denmark (24%), Greece (21%) and Sweden (21%) [6]. Furthermore, Laucht and Schmid reported a correlation between the number of cigarettes smoked by 15-year-olds and a young age of smoking onset [7]. Additionally, the use of water pipes has increased in the past few years in Germany [8]. Maziak has indicated that water pipes pave the way to cigarette smoking and have similarly deleterious effects on human health [9]. Therefore, the development of scientifically evaluated and optimised smoking prevention programmes for adolescents is imperative.

A popular school-based tobacco prevention programme, which has been implemented in many countries in the European Union, is the Smoke-free Class Competition [10-12]. However, a Cochrane systematic review from 2012 concluded that this programme was not effective for primary or secondary smoking prevention in adolescents [12].

In addition, it is imperative to sensitise prospective physicians to tobacco addiction and associated responsibilities within communities [13]. Recent studies from prestigious international and national medical faculties indicate that tobacco addiction is drastically undertreated by physicians in comparison with other chronic conditions, mainly because of lack of motivation, skills and knowledge [14-16]. The authors of these studies concluded that alternative models of engagement are

needed to enhance the use of effective treatments for tobacco addiction and to raise awareness among physicians.

A key advantage of the Education Against Tobacco (EAT) programme is that medical students learn to take tobacco-related responsibilities in their role as health educators and to discuss tobacco-associated diseases in an understandable way [17]. These aspects not only facilitate school-based prevention but also provide education for cooperative decision-making in inpatient settings [17, 18]. To the best of our knowledge, no school-based programme for tobacco prevention delivered by medical students has been evaluated to date.

A school-based smoking prevention programme delivered by medical students

About 3 years after medical student Titus J. Brinker founded EAT (January 2012), the programme has more participating mentors (700 medical students) and interactively educates more secondary school students (16,000) per year than any other known school-based physician-delivered or medical-student-delivered tobacco prevention programme in Germany or, as far we know, worldwide. It currently costs about EUR 20 per participating class and is therefore less expensive than comparable programmes. The EAT group at the University of Gießen had the highest level of experience and the most participating EAT schools in October 2013 and therefore was considered as an adequate platform to evaluate the short-term effects of EAT from October 2013 to July 2014.

Secondary school programmes that involve physicians as health educators have already been evaluated. “Non-smoking is Cool” (NiC), a German physician-delivered intervention using a combined social influence and fear-based approach, published its evaluation in 2013 [19]. Addressing grades five to six of all secondary school

types (total sample size reported: 1,359 students), NiC proved to be exclusively effective in grammar schools, where it reduced the onset of smoking in the intervention group by 50% compared with the control group at 3- and 9-month follow-up assessments. However, it was ineffective for secondary schools with a lower education level and in secondary tobacco prevention [19].

In addition, data were published in 2012 on a physician-delivered programme called “Students in the Hospital” for secondary school students with a median age of 16 years in Berlin. This programme achieved significant positive results in primary prevention using a multimodal approach at half year follow-up (odds ratio (OR): 4.14; 95% confidence interval (CI): 1.66–10.36) [20]. However, no secondary preventive effect could be measured.

The aim of this study was to determine the efficacy of the EAT intervention in primary and secondary prevention [17]. The primary endpoint was defined in our study protocol as the prevalence between smokers and non-smokers in the two study arms 6 months after the intervention [17]. In addition, we aimed to assess whether the programme is equally effective for participants of different gender, social and cultural backgrounds [17].

Methods

Design

As defined in our protocol, the survey was designed as a quasi-experimental prospective evaluative study with two measurements (baseline and 6 months post-intervention) [17]. The study period was October 2013 until July 2014. Participants in

the two study groups (intervention and control groups) were questioned up to 2 weeks in advance of the intervention (t1) and 6 months thereafter (t2) (Figure 1).

Randomization was impossible as schools refused to participate when informed that intervention classes would be randomly externally selected. Thus, we asked the participating schools in advance to split their grades themselves into two class-groups (intervention vs. control classes) with the same performance levels (parallel classes). All intervention classes in our sample had parallel classes.

<Figure 1.pdf as separate file>

Participants

1,689 individual participants were included of which 1,200 completed the questionnaire at both time points (t1+t2). Students aged 10 to 15 years attending grades six to eight of a secondary general, intermediate, grammar or comprehensive school were eligible [17].

Intervention

The programme consisted of two interactive 60-minute modules. The first part was presented by two to six medical students and a patient with a tobacco-related disease to all pupils at the same time inside a large room within the school. It consisted of a PowerPoint (Microsoft; Redmond, WA, USA) presentation in which the participants were encouraged to make their own well-informed decisions (social competence approach). The university hospital patient with a smoking-related disease was interviewed about his reasons for starting to smoke and the influence

tobacco consumption had on his life. Again, the students were encouraged to ask the patient their own questions.

The second part took place in an interactive classroom setting in which two medical students (usually a man and a woman) tutored one class. As reported in our study protocol, both modules focused on educating adolescents about the strategies of the tobacco industry to influence their decision in a non-objective manner (social influence) and on peer pressure (social influence), decision-making and skills for coping with challenges in their life in a healthy way (social competence) [17]. The participants also discussed information relevant for their age group, e.g., why non-smokers usually look more attractive, have more money to buy things, or succeed in sports. The programme focussed on not scaring but educating its participants in an interactive manner. Accordingly, EAT used a combined social influence and social competence approach, which has been described as the most effective approach in the recently published Cochrane review [17, 21].

Data collection

We used a written survey questionnaire that was developed to collect data at both time points (t1 and t2) [17]. In addition to the socio-demographic data (age, gender, school type), it captured the smoking status of the school students concerning water pipe use and cigarette consumption.

The questionnaire contained numerous items that have already been included in similar investigations. The questions about the smoking status and the frequency of smoking referred to the evaluation of the school-based smoking prevention programmes in Heidelberg titled “ohne kippe” (no butts) and in Berlin titled “Students

in the Hospital", as well as to the results of the German Health Interview and Examination Survey for Children and Adolescents published by Lampert and Thamm [20, 22, 23]. As described in our study protocol, we tested and optimised the questionnaire in accordance with the Good Epidemiologic Practice guidelines [24].

The class teachers individually supervised their classes during the completion of the questionnaire. To maximise the confidentiality of the intervention, the questionnaires were placed in envelopes that were instantly sealed and co-signed by the responsible class teachers immediately after completion. The envelopes were opened and the data entry and analysis was performed under the supervision of one of the authors (DAG) at the Goethe University of Frankfurt.

Outcomes

As predefined, the primary end point was the prevalence of smokers and non-smokers in the two study arms at 6 months post-intervention. The percentage of former smokers and new smokers in the two groups were studied as secondary outcome measures. A smoker was defined as a pupil who claimed to smoke at least "once a month" within the survey. The pupils who claimed not to smoke at all were defined as non-smokers.

Statistical analysis

Sample size calculation

Despite the exploratory character of our study, we aimed for a realistic sample size on the basis of effect sizes of physician-delivered programmes in accordance with our study protocol ($p<0.05$) [17, 19, 20]. Taking into account the loss to follow-up effect in the "Students in the Hospital" programme (17.8%), we calculated a sample size of n1 = 514 and

n2 = 514 to produce a total sample size of 1,028 [20]. However, considering the risk of smaller effects we strived for a sample size larger than 1,028.

Analysis

To examine baseline differences we used χ^2-tests (categorical variables) and t-tests (continuous variables). The effects of predictors (gender, culture and social characteristics) on smoking behaviour after 6 months (t2) were calculated by logistic regression analysis, a state-of-the-art technique for the evaluation of the effectiveness of prevention programmes in prospective studies [22, 25, 26]. The significance level was 5% for t-tests (double-sided) and 95% for confidence intervals (double-sided). Statistical analysis was performed using SPSS Statistics Version 22 by IBM (Armong, USA).

Results

Recruitment

A total of 1,689 eligible secondary school students were recruited from November 2012 to October 2013. All participants fulfilled the inclusion criteria. Students aged 10 to 15 years attending grades six to eight of a secondary general, intermediate, grammar or comprehensive school were eligible [17]. Baseline data of 1,474 participants were collected from October 2013 to January 2014. Follow-up data were collected from April to July 2014. 1,200 participants provided data at both time points (t1 + t2) that was used for analysis. The loss to follow-up effect was 18.6% (N=274). The participants who dropped out at follow-up (t2) showed no systematic bias with regard to study group or smoking status (p = 0.84).

Baseline data

The median age of the 1,474 eligible participants at baseline (Fig. 1) was 13 years (mean age 12.55 years; range 11–15 years) and 52.0% were female. Of the participants, 43.9% attended grammar schools and the remaining 56.1% attended comprehensive schools (which were classified in the survey as "lower education level"). The survey identified 6.4% of participants as smokers at baseline. There were no significant differences concerning the number of smokers in both groups (p=0.088; Table 1).

Table 1: Descriptive data at baseline

Variables	Intervention group (N=713)	Control group (N=761)	P-Value
Gender (n) (%) • Male • Female	 349 (49.5) 356 (50.5)	 352 (46.6) 404 (53.4)	 0.261
Age • Mean (±SD)	 12.47 (0.79)	 12.64 (0.78)	 <0.01
Schooltype (n) (%) • Grammar • Comprehensive	 281 (39.4) 432 (60.6)	 366 (48.1) 395 (51.9)	 <0.01/ 0.046[a]
Migrant BG (n) (%)	182 (27.5)	221 (31.3)	0.122
Smoking status (n) (%) Smokers Non Smokers	 54 (7.6) 659 (92.4)	 41 (5.4) 720 (94.6)	 0.088

Smoking behaviour of non-smokers, (n) (%)			
Never smoked	615 (95.1)	683 (97.0)	0.021
Stopped less than 6 months beforehand	9 (1.4)	12 (1.7)	
Stopped more than 6 months beforehand	23 (3.6)	9 (1.3)	
Smoking behavior of smokers at baseline. (n) (%)			
Cigarettes (monthly-daily)	32 (60.4)	21 (39.6)	0.435
Daily	8 (25.0)	4 (19.1)	0.613
More than once per week	2 (6.3)	2 (9.5)	0.659
Once per week	4 (12.5)	3 (14.3)	0.851
Monthly	18 (56.3)	12 (57.1)	0.683
Waterpipe-smokers (monthly-daily)	34 (58.6)	24 (41.4)	0.661
Daily	3 (8.8)	0 (0)	0.135
More than once per week	6 (17.7)	3 (12.5)	0.594
Once per week	5 (14.7)	2 (8.3)	0.463
Monthly	20 (58.8)	19 (79.2)	0.104

a) p-value adjusted for class size (classes in the intervention group were systematically smaller than in the control group (mean class size = 23.96 vs. 25.07 in control group; $p<0.01$))

Follow-up at 6 months

Table 2: Nominal and percentage effects of the intervention on the smoking status (secondary outcomes)

		Prospective smoking status (t1-t2)			
		stays nonsmoker	starts smoking	stops smoking	stays smoker
control group	N	562	31	7	19
	% in group	90.8%	5.0%	1.1%	3.1%
intervention group	N	511	29	27	14
	% in group	88.0%	5.0%	4.6%	2.4%

Total	N	1073	60	34	33
	% in group	89.4%	5.0%	2.8%	2.8%

Analyses of the data were by original assigned groups: There were 581 pupils in the intervention group and 619 pupils in the control group who had participated in the survey at both time points (prospective sample = 1,200 pupils). There was a significant effect ($p<0.01$) for the defined primary endpoint. We had a total of 67 smokers at t1 which did not drop out at t2 of which 26 were in the control group and 41 in the intervention group. At six months follow up, 27 (4.6%) smokers in the intervention group had quitted but only 7 (1.1%) smokers in the control group were abstinent (Table 2). In the control group, the percentage of students who claimed to be smokers nearly doubled from 26 smokers (4.2%; t1) to 50 smokers (8.1%; t2) whereas it remained almost the same in the intervention group (41 smokers (7.1%) at t1 vs. 43 smokers (7.4%) at t2). However, no primary preventive effect was measured.

Table 3: Multiple logistic regression analysis (main effects) for prediction of quitting smoking by smokers (n=67)

Variables	Standard Error	P-Value	Odds Ratio	95% Confidence Interval	
				Lower	Upper
Age	0.39	0.015	.385	.178	.830
Gender (ref. female)	0.56	0.633	1.308	.434	3.946
Intervention group (ref. Control)	0.60	0.004	5.626	1.736	18.237
Comprehensive school (Ref. Grammar school)	0.65	0.160	.402	.112	1.435

The chance of quitting smoking was more than five times higher in the intervention group according to logistic regression analysis (OR: 5.63; 95% CI: 1.74–18.24; p<0.01; Table 3). As can also be seen in Table 3, age seems to have a significant effect on smoking status: increasing the age by 1 year within our sample (11–15 years) reduces the chance to stop smoking by 61.5% (OR: 0.385; 95% CI: 0.18–0.83).

Because the sample sizes for smokers in the intervention group were relatively small, we cannot prove a systematic co-dependency between effectiveness and migrant background, gender or a higher level of education.

Legal approval

In accordance with Good Epidemiologic Practice guidelines, an ethics waiver and all legal permissions were obtained from the responsible institutions before data collection started as described in our study protocol [17, 24].

Discussion

School-based physician-delivered tobacco prevention programmes have shown short-term and long-term effectiveness but are usually expensive and tutor relatively few students [19, 20, 27]. In addition, it is imperative to sensitise prospective physicians to tobacco addiction and associated responsibilities within communities [13, 28].

In this study, we report a significant secondary preventive effect of a widespread intervention delivered by volunteer medical students to secondary school students

(11–15 years); at 6 months of follow-up, the odds ratio was 5.63 to stop smoking in the intervention vs. the control group (p<0.01; CI: 1.74–18.24).

No medical-student-delivered school-based tobacco prevention programme has been evaluated to date. However, the recent Cochrane review on school-based tobacco prevention highlighted the need for the evaluation of novel, cost-effective and widespread interventions, especially as the most widespread school-based programme (Smoke-free Class Competition) proved ineffective in adolescents [12, 21].

Limitations

Our data indicate that the quasi-experimental design of our study caused some selection bias as the number of smokers (7.6% vs. 5.4%) and former smokers (5% vs. 3%) was higher in the intervention group at t1. The teachers probably insisted on choosing classes at higher risk for smoking as intervention classes which is also illustrated by a significant higher number of pupils visiting classes with a lower education level within the intervention group (p<0.01) as smoking correlates with low education [19]. In addition, cluster effects could not be excluded, because the intervention and control groups attended the same schools.

Our study relies on self-reports obtained from adolescents via questionnaire; therefore, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, possibly because of social desirability bias. This bias could only be excluded by using expensive methods such as testing for cotinine (a metabolite of nicotine) in the saliva, blood or urine of the students. However, recent publications indicate that self-reports via questionnaire are relatively precise in

tobacco research excluding pregnant women and patients with tobacco-related diseases [29].

As we had suspected, to measure a primary preventive effect rather than a secondary preventive effect, we had to perform our logistic regression analysis with a relatively small sample size. A recent Cochrane review indicates that a half year follow-up might be too short to measure significant primary preventive effects of a programme with a combined social competence and social influence approach, because these programmes usually provide measurable effects after more than 1 year of follow-up [21].

Generalisation

The participants came from the two most prevalent German school types (comprehensive and grammar schools), which makes our results transferable to the majority of German students in the age group 11–15 years. However, as our research is not multinational, prevention programmes delivered by medical students might not be useful for students of all ethnic and cultural backgrounds.

Interpretation

Our data reveal that motivating students to quit smoking using EAT works significantly better at a young age, which suggests that younger smokers are not as addicted as older smokers but are more likely to be in the phase of experimentation. In accordance, most of the smoking participants in the survey claimed to smoke less than once a day. The discussed selection bias may have negatively affected our results for primary prevention. However, the participants who started smoking also showed experimentation characteristics (most of them smoking less than once a

day). Thus, we hypothesise that in this young age group it may be more difficult to reduce curiosity and to avoid experimentation behaviour in the short-term than it is to convince those who have already experimented with cigarettes to stop smoking. This thesis is supported by numerous publications addressing this age group, which show no primary preventive effect at half year follow-up with various approaches [21]. Another explanation for the short-term result of no primary prevention effect can be found within the recent Cochrane review: Combined social competence and social influence programmes such as EAT did not show primary preventive effectiveness at less than 1 year follow-up within the meta analysis [21]. Thus, our intervention might also show a primary preventive effect at longer follow-up [21].

The implementation of cost-effective measures to prevent smoking in adolescents and, moreover, the sensitisation of prospective physicians to tobacco-attributable diseases, tobacco prevention, and improved communication of these issues in medicine is addressed by our programme [14-16, 18].

Long-term evaluation of the programme with a larger sample size to measure interaction effects, international research and the optimisation of the programme will be the focus of future investigations.

Conclusions

In conclusion, the EAT programme shows a significant secondary preventive effect in secondary school students at 6 months of follow-up (OR: 5.63; CI: 1.74–18.24; p<0.01). Thus, medical students can effectively be involved in school-based tobacco prevention programmes. Further research and long-term evaluation is needed to confirm this *post hoc* finding.

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Protocol

The protocol of this study is freely accessed at BMJ Open [17]:

http://bmjopen.bmj.com/content/4/7/e004909.full

Authors' contributions

TJB conducted the study, invented, designed and organised the intervention, wrote the manuscript, contributed to the design of the study, coordinated and conducted data entry and performed the statistical analysis. DAG contributed to the design of the study, supervised data entry and proofread the manuscript. SS-B contributed to the design of the study and the analysis of data and proofread the manuscript. WS supported the conduction of the study and proofread the manuscript. DK supported the conduction of data entry and proofread the manuscript. All authors read and approved the final manuscript. This study is part of a thesis project (TJB).

Competing interests

The authors declare that they have no competing interests.

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grant from any funding agency in the public, commercial or not-for-profit sectors.

Data sharing statement

We are not allowed to publish our full data online due to German data protection laws. The original paper based questionnaires are stored at our Institute at the Goethe-University in Frankfurt for the next ten years for documentation purposes.

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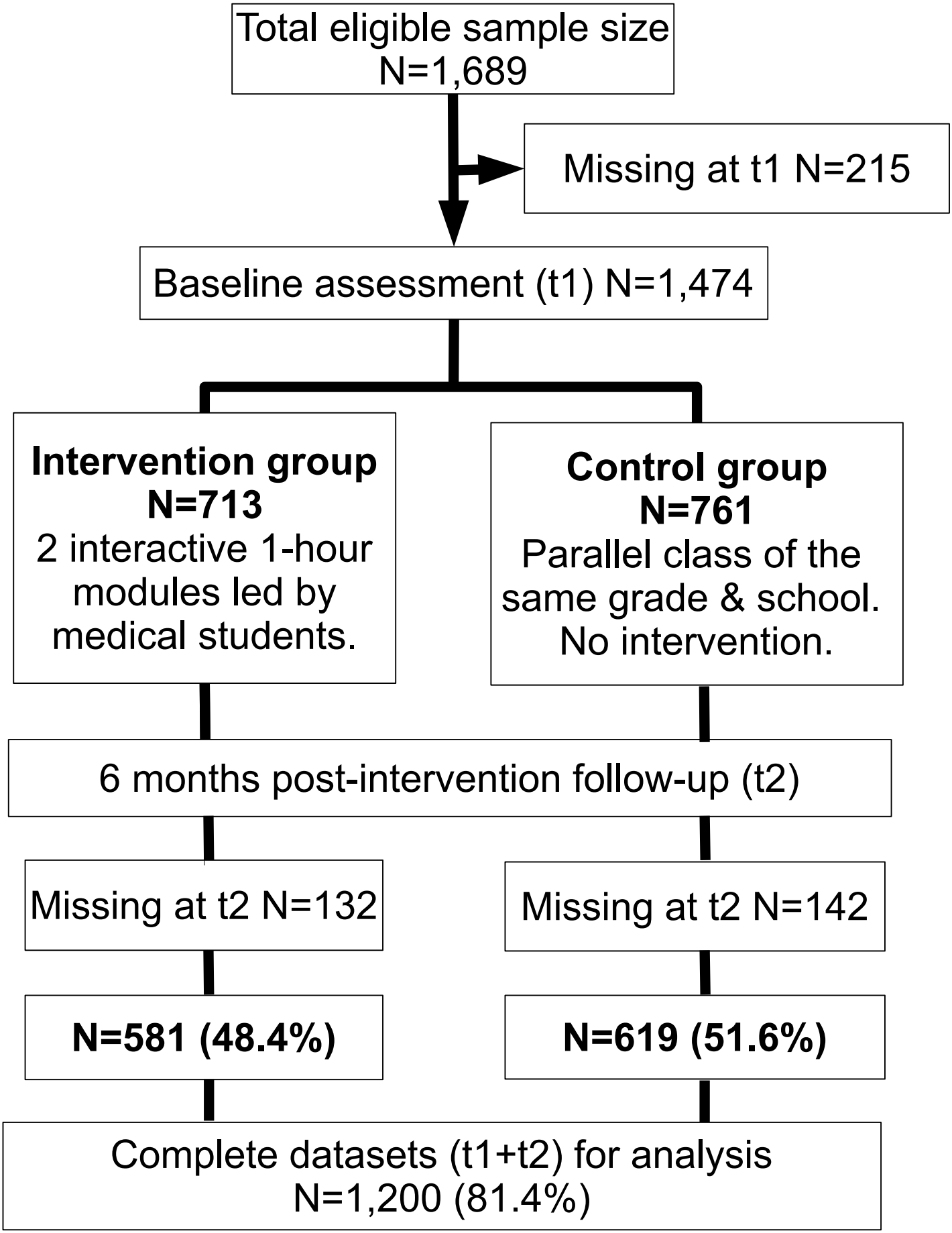

Figure 1
Study design.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **checked**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **checked**
Objectives	3	State specific objectives, including any prespecified hypotheses **checked**
Methods		
Study design	4	Present key elements of study design early in the paper **checked**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **checked**
Participants	6	(*a*) *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls **checked**
		(*b*) *Case-control study*—For matched studies, give matching criteria and the number of controls per case **checked**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **checked**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **checked**
Bias	9	Describe any efforts to address potential sources of bias **checked**
Study size	10	Explain how the study size was arrived at **checked**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **checked**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **checked**
		(*b*) Describe any methods used to examine subgroups and interactions **checked**
		(*c*) Explain how missing data were addressed **checked**
		Case-control study—If applicable, explain how matching of cases and controls was addressed **checked**
		(*e*) Describe any sensitivity analyses **checked**

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed **cbecked**
		(b) Give reasons for non-participation at each stage **checked**
		(c) Consider use of a flow diagram **checked**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **checked**
		(b) Indicate number of participants with missing data for each variable of interest **checked**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure **checked**
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **checked**
		(*b*) Report category boundaries when continuous variables were categorized **checked**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **checked**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **checked**
Discussion		
Key results	18	Summarise key results with reference to study objectives **checked**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **checked**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **checked**
Generalisability	21	Discuss the generalisability (external validity) of the study results **checked**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **checked**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Education Against Tobacco (EAT): a quasi-experimental prospective evaluation of a multinational medical-student-delivered smoking prevention programme for secondary schools in Germany

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Education Against Tobacco (EAT): a quasi-experimental prospective evaluation of a multinational medical-student-delivered smoking prevention programme for secondary schools in Germany

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ABSTRACT

Objectives: To evaluate the multinational medical-student-delivered tobacco prevention programme for secondary schools for its effectiveness to reduce the smoking prevalence among 11-15 year olds in Germany at half year follow-up.

Setting: We used a prospective quasi-experimental study design with measurements at baseline (t1) and 6 months post-intervention (t2) to investigate an intervention in 8 German secondary schools. The participants were split into intervention- and control classes in the same schools and grades.

Participants: A total of 1,474 eligible participants of both genders at the age of 11-15 years were involved within the survey for baseline assessment of which 1,200 completed the questionnaire at six months follow-up (=longitudinal sample). The schools participated voluntarily. The inclusion criteria were age (10-15 years), grade (6-8) and school type (regular secondary schools).

Intervention: Two 60-minute school-based modules delivered by medical students.

Primary and secondary outcome measures: The primary end point was the difference from t1 to t2 of the smoking prevalence in the control group versus the difference from t1 to t2 in the intervention group (difference of differences approach). The percentage of former smokers and new smokers in the two groups were studied as secondary outcome measures.

Results: In the control group, the percentage of students who claimed to be smokers doubled from 4.2% (t1) to 8.1% (t2), whereas it remained almost the same in the intervention group (7.1% (t1) to 7.4% (t2); p=0.01). The chance of quitting smoking was almost six times higher in the intervention group (total of 67 smokers at

t1; 27 (4.6%) quitted in the intervention- and 7 (1.1%) in the control group; odds ratio: 5.63; 95% confidence interval: 2.01–15.79; p<0.01). However, no primary preventive effect was found.

Conclusion: We report a significant secondary preventive (smoking cessation) effect at six months follow-up. Long-term evaluation is planned.

Keywords: medical students, tobacco prevention, secondary schools, smoking cessation, adolescents, school-based prevention

Strengths and limitations of this study

- No medical-student-delivered school-based tobacco prevention programme has been evaluated for its preventive effect to date.
- It is imperative to sensitize prospective physicians to tobacco prevention.
- The quasi-experimental design of this study caused a selection bias due to the lack of randomization.
- As control classes were located in the same schools, cluster effects could not be excluded entirely.
- Our follow-up data was only collected six months after the intervention due to organisational reasons. Thus, we were not able to determine long-term effects.

Background

Smoking is the biggest external cause of non-contagious disease and is responsible for more deaths than obesity both globally and in high-income countries such as Germany or the USA [1, 2].

The 2011 European School Survey Project on Alcohol and Other Drugs report revealed that a higher percentage of 16-year-old pupils from Germany claimed to have smoked in the past 30 days (33%) than pupils from Denmark (24%), Greece (21%) and Sweden (21%) [3]. Additionally, the use of water pipes has increased in the past few years in German adolescents and was described to have similarly deterious effects on human health [4, 5].

Less popular secondary school programmes that involve physicians as health educators have already been evaluated showing significantly positive effects [6] [7]. However, they are not broadly available.

A popular school-based tobacco prevention programme, which has been implemented in many countries in the European Union, is the Smoke-free Class Competition (called “Be Smart Don’t Start”) In Germany [8-10]. However, a Cochrane systematic review from 2012 concluded that this programme was not effective for primary or secondary smoking prevention in adolescents [10].

Recent studies from prestigious international and national medical faculties indicate that tobacco addiction is drastically undertreated by physicians in comparison with other chronic conditions, mainly because of lack of motivation, skills and knowledge [11-13]. Novel ways of engagement for prospective physicians was demanded [11]. A key advantage of the Education Against Tobacco (EAT) programme is that medical students learn to take tobacco-related responsibilities in their role as health educators in schools and to discuss tobacco-associated diseases in an understandable way. These aspects not only facilitate school-based prevention but also provide education for cooperative decision-making in inpatient settings [14, 15]. The multinational programme EAT is currently enrolled in over 40 medical schools in

Germany, Switzerland, Austria, Sudan, Bosnia and Herzegovina, Bangladesh and the United States.

The aim of this study was to determine the effectiveness of the school-based EAT intervention in smoking initiation prevention and smoking cessation in Germany [14]. The primary end point was the difference from t1 to t2 of the smoking prevalence in the intervention group versus the difference from t1 to t2 in the control group (difference of differences approach) [14]. In addition, we aimed to assess whether the programme is equally effective for participants of different gender, social and cultural backgrounds [14].

Methods

Design

As defined in our protocol, the survey was designed as a quasi-experimental prospective evaluative study with two measurements (baseline and 6 months post-intervention) [14]. The study period was October 2013 until July 2014. Participants in the two study groups (intervention and control groups) were questioned up to 2 weeks in advance of the intervention (t1) and 6 months thereafter (t2) (Figure 1).

Randomization was impossible as schools refused to participate when informed that intervention classes would be randomly externally selected. Thus, we asked the participating schools in advance to split their grades themselves into two class-groups (intervention vs. control classes) with the same performance levels (parallel classes). All intervention classes in our sample had parallel classes.

<Figure1.pdf as separate file>

Participants

A total of 1,689 eligible secondary school students from 8 eligible schools were recruited from November 2012 to October 2013. All participants fulfilled the inclusion criteria. Students aged 10 to 15 years attending grades six to eight of a secondary general, intermediate, grammar or comprehensive school were eligible [14]. Baseline data of 1,474 participants were collected from October 2013 to January 2014. Follow-up data were collected from April to July 2014. 1,200 participants provided data at both time points (t1 + t2) that was used for analysis. The loss to follow-up effect was 18.6% (N=274).

Attrition Analysis

The participants who dropped out at follow-up (t2) were analyzed with logistic regression analysis and showed no systematic bias with regard to the interaction between study group and smoking status (p=0.19) or study group and gender (p=0.725) or study group and school type (p=0.082). However, it showed a systematic bias for study group and age (p=0.045; OR=0.709; 95% CI: 0.51-0.99) meaning that significantly more young people dropped out of the intervention group vs. the control group.

Intervention

The intervention consisted of two interactive 60-minute modules. The first part was presented by two to six medical students and a patient with a tobacco-related disease to all pupils at the same time inside a large room within the school. It

consisted of a PowerPoint (Microsoft; Redmond, WA, USA) presentation in which the participants were encouraged to make their own well-informed decisions (social competence approach). The university hospital patient with a smoking-related disease was interviewed about his reasons for starting to smoke and the influence tobacco consumption had on his life. Again, the students were encouraged to ask the patient their own questions.

The second part took place in an interactive classroom setting in which two medical students (usually a man and a woman) tutored one class. As reported in our study protocol, both modules focused on educating adolescents about the strategies of the tobacco industry to influence their decision in a non-objective manner (social influence) and on peer pressure (social influence), decision-making and skills for coping with challenges in their life in a healthy way (social competence) [14]. The participants also discussed information relevant for their age group, e.g., why non-smokers usually look more attractive, have more money to buy things, or succeed in sports. The programme focussed on not scaring but educating its participants in an interactive manner. Accordingly, EAT used a combined social influence and social competence approach, which has been described as the most effective approach in the recently published Cochrane review [14, 16].

Data collection

We used a paper pencil survey questionnaire that was developed to collect data in the class room via the class teachers at both time points (t1 and t2) [14]. In addition to the socio-demographic data (age, gender, school type), it captured the smoking status of the school students concerning water pipe use and cigarette consumption.

The questionnaire contained numerous items that have already been included in similar investigations. The questions about the smoking status and the frequency of smoking referred to the evaluation of the school-based smoking prevention programmes in Heidelberg titled “ohne kippe” (no butts) and in Berlin titled “Students in the Hospital”, as well as to the results of the German Health Interview and Examination Survey for Children and Adolescents published by Lampert and Thamm [7, 17, 18]. As described in our study protocol, we tested and optimised the questionnaire in accordance with the Good Epidemiologic Practice guidelines [19].

The class teachers individually supervised their classes during the completion of the questionnaire. To maximise the confidentiality of the intervention, the questionnaires were placed in envelopes that were instantly sealed and co-signed by the responsible class teachers immediately after completion. The envelopes were shipped to the Goethe University of Frankfurt where they were opened and the data entry and analysis was performed under the supervision of two of the authors (DAG and DK).

Outcomes

The primary end point was the difference from t1 to t2 of the smoking prevalence in the control group versus the difference from t1 to t2 in the intervention group (difference of differences approach). The percentage of former smokers and new smokers in the two groups were studied as secondary outcome measures. A smoker was defined as a pupil who claimed to smoke at least “once a month” within the survey. The pupils who claimed not to smoke at all were defined as non-smokers.

Statistical analysis

Analysis

To examine baseline differences we used χ^2-tests (categorical variables) and t-tests (continuous variables). The effects of predictors (gender, culture and social characteristics) on smoking behaviour after 6 months (t2) were calculated by robust panel logistic regression analysis. The significance level was 5% for t-tests (double-sided) and 95% for confidence intervals (double-sided). Statistical analysis was performed using SPSS Statistics Version 23 by IBM (Armong, USA) and STATA 14 by StataCorp (Texas, USA). In our sample the group allocation was not on the individual level but on the class level. In order to take into account this clustering statistically we used robust panel logistic regression (xtlogit proceduce with vce (cluster) option). This procedure was also used to calculate the difference from t1 to t2 of the smoking prevalence in the control group versus the difference from t1 to t2 in the intervention group (our primary endpoint) by the help of STATA 14 by StataCorp (Texas, USA).

Legal approval

In accordance with Good Epidemiologic Practice guidelines, an ethics waiver and all legal permissions were obtained from the responsible institutions before data collection started as described in our study protocol [14, 19].

Results

Baseline data

The median age of the 1,474 eligible participants at baseline (Fig. 1) was 13 years (mean age 12.55 years; range 11–15 years) and 52.0% were female. Of the

participants, 43.9% attended grammar schools and the remaining 56.1% attended comprehensive schools (which were classified in the survey as “lower education level”). The survey identified 6.4% of participants as smokers at baseline. There were no significant differences concerning the number of smokers in both groups (p=0.088; Table 1).

Table 1: Descriptive data at baseline

Variables	Intervention group (N=713)	Control group (N=761)	P-Value
Gender (n) (%) • Male • Female	 349 (49.5) 356 (50.5)	 352 (46.6) 404 (53.4)	 0.261
Age • Mean (±SD)	 12.47 (0.79)	 12.64 (0.78)	 <0.01
Schooltype (n) (%) • Grammar • Comprehensive	 281 (39.4) 432 (60.6)	 366 (48.1) 395 (51.9)	 <0.01/ 0.046[a]
Migrant BG (n) (%)	182 (27.5)	221 (31.3)	0.122
Smoking status (n) (%) Smokers Non Smokers	 54 (7.6) 659 (92.4)	 41 (5.4) 720 (94.6)	 0.088
Smoking behaviour of non-smokers, (n) (%) Never smoked Stopped less than 6 months beforehand Stopped more than 6 months beforehand	 615 (95.1) 9 (1.4) 23 (3.6)	 683 (97.0) 12 (1.7) 9 (1.3)	 0.021
Smoking behaviour of smokers (n) (%) *Cigarettes (monthly-daily)* Daily More than once per week	 32 (60.4) 8 (25.0)	 21 (39.6) 4 (19.1)	 0.435 0.613

Once per week	2 (6.3)	2 (9.5)	0.659
Monthly	4 (12.5)	3 (14.3)	0.851
	18 (56.3)	12 (57.1)	0.683
Waterpipe-smokers (monthly-daily)	34 (58.6)	24 (41.4)	0.661
Daily	3 (8.8)	0 (0)	0.135
More than once per week	6 (17.7)	3 (12.5)	0.594
Once per week	5 (14.7)	2 (8.3)	0.463
Monthly	20 (58.8)	19 (79.2)	0.104

a) p-value adjusted for class size (classes in the intervention group were systematically smaller than in the control group (mean class size = 23.96 vs. 25.07 in control group; p<0.01))

Follow-up at 6 months

Analyses of the data were by original assigned groups: There were 581 pupils in the intervention group and 619 pupils in the control group who had participated in the survey at both time points (baseline sample=1,474; prospective sample=1,200 pupils; loss to follow-up=274 pupils).

Primary Endpoint

There was a significant effect for the defined primary endpoint (OR: 0.35; 95% CI: 0.15-0.78; p=0.01) calculated with the prospective sample of 1,200 participants (Table 2): The percentage of students who claimed to be smokers doubled from 4.2% (t1) to 8.1% (t2) in the control group, whereas it remained almost the same in the intervention group (7.1% (t1) to 7.4% (t2)). The development in terms of smoking prevalence of the two study groups was significantly different (p=0.01; Table 2).

Table 2: Primary endpoint calculated by robust panel logistic regression (xtlogit proceduce with vce (cluster) option)

Variable	Standard Error	P-Value	Odds Ratio	95% Confidence Interval	
				Lower	Upper
time#group#endline#intervention group	0.14	0.01	0.35	0.15	0.78

Secondary Outcomes

At six months follow up, 27 (4.6%) smokers in the intervention group had quitted but only 7 (1.1%) smokers in the control group were abstinent (Table 3). However, no primary preventive (initiation prevention) effect was found as in both groups 5.0% of the prospective sample started to smoke (Table 3).

Table 3: Nominal and percentage effects of the intervention on the smoking status (secondary outcomes)

		Prospective smoking status (t1-t2)			
		stays nonsmoker	starts smoking	stops smoking	stays smoker
control group	N	562	31	7	19
	% in group	90.8%	5.0%	1.1%	3.1%
intervention group	N	511	29	27	14
	% in group	88.0%	5.0%	4.6%	2.4%
Total	N	1073	60	34	33
	% in group	89.4%	5.0%	2.8%	2.8%

The chance of quitting smoking was more than five times higher in the intervention group according to robust panel logistic regression analysis (OR: 5.63; 95% CI: 2.01–15.79; p<0.01; Table 4). As can also be seen in Table 4, age seems to have a

significant effect on smoking status: increasing the age by 1 year within our sample (11–15 years) reduces the chance to stop smoking by 61% (OR: 0.39; 95% CI: 0.19–0.78). Students from comprehensive school within our prospective sample have a 60% lower chance of quitting smoking when compared with students from grammar schools (OR: 0.40; 95% CI: 0.18-0.91; p=0.03).

Because the sample sizes for smokers in the intervention group were relatively small, we cannot prove a systematic co-dependency between quitting smoking and migrant background or gender.

Table 4: Robust panel logistic regression analysis (main effects) for prediction of quitting smoking by smokers (n=67)

Variables	Robust Standard Error	P-Value	Odds Ratio	95% Confidence Interval	
				Lower	Upper
Age	0.14	<0.01	0.39	0.19	0.78
Gender (ref. female)	0.74	0.64	1.31	0.43	3.98
Intervention group (ref. Control)	2.96	<0.01	5.63	2.01	15.79
Comprehensive school (Ref. Grammar school)	0.17	0.03	0.40	0.18	0.91

Discussion

School-based physician-delivered tobacco prevention programmes have shown short-term and long-term effectiveness but are usually expensive and tutor relatively few students [6, 7, 20]. At the same time, it is imperative to sensitise prospective physicians to tobacco addiction and associated responsibilities within communities

[21, 22]. About 3 years after medical student Titus J. Brinker founded EAT (January 2012), the programme has more participating mentors (700 medical students) and interactively educates more secondary school students (16,000) per year than any other known school-based physician-delivered or medical-student-delivered tobacco prevention programme in Germany or, as far we know, worldwide. It currently costs about EUR 20 per participating class and is therefore less expensive than comparable programmes.

In this study, we report a significant effect to reduce smoking prevalence of a widespread intervention delivered by volunteer medical students to secondary school students (11–15 years); at 6 months of follow-up, the odds ratio was 5.63 to stop smoking in the intervention vs. the control group (CI: 2.01–15.79; p<0.01). To the best of our knowledge, this study is the first evaluation of a medical student-delivered school-based tobacco intervention.

Interpretation

Our data reveal that motivating students to quit smoking using EAT works significantly better at a young age (p<0.01), which suggests that younger smokers are not as addicted as older smokers but are more likely to be in the phase of experimentation. In accordance, most of the smoking participants in the survey claimed to smoke less than once a day. The participants who started smoking also showed experimentation characteristics (most of them smoking less than once a day). Thus, we hypothesise that in this young age group it may be more difficult to reduce curiosity and to avoid experimentation behaviour in the short-term than it is to convince those who have already experimented with cigarettes to stop smoking. This

thesis is supported by numerous publications addressing this age group, which show no primary preventive effect at half year follow-up with various approaches [16]. Another explanation for the short-term result of no primary prevention effect can be found within the recent Cochrane review: Combined social competence and social influence programmes such as EAT did not show primary preventive effectiveness at less than 1 year follow-up within the meta analysis [16]. Thus, our intervention might also show a primary preventive effect at longer follow-up. In addition, we hypothesize that the effect on reducing smoking prevalence in the intervention group would have been larger in a randomised experimental setting as we found two biases both potentially shrinking the effect of the intervention (see below).

The implementation of cost-effective measures to prevent smoking in adolescents and, moreover, the sensitisation of prospective physicians to tobacco-attributable diseases, tobacco prevention, and improved communication of these issues in medicine is addressed by our programme [11-13, 15].

Limitations

Our data indicate that the quasi-experimental design of our study caused some selection bias as the number of smokers (7.6% vs. 5.4%) and former smokers (5% vs. 3%) was higher in the intervention group in the complete baseline sample (cross sectional data). The teachers probably insisted on choosing classes at higher risk for smoking as intervention classes which is also illustrated by a significant higher number of pupils visiting classes with a lower education level within the intervention group ($p<0.01$) as smoking correlates with low education [6]. Accordingly, our robust panel logistic regression analysis on our prospective smoker subgroup revealed that students from comprehensive schools have a significantly lower chance to quit

smoking (p=0.03). As young age is also a significant predictor of quitting in our sample (p<0.01), the reported attrition bias showing that systematically more young students dropped out in our intervention group (p=0.045) might have lowered the effect of the intervention. Thus, we report two systemic biases in our quasi-experimental design considering age (attrition bias; p=0.045) and school type (selection bias; significantly more comprehensive school students and less grammar school students in our intervention group at baseline; p<0.01) which both rather decrease the measured effect in reducing smoking prevalence of the intervention. In addition, cluster effects could not be excluded, because the intervention and control groups attended the same schools.

Our study relies on self-reports obtained from adolescents via questionnaire; therefore, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, possibly because of social desirability bias. This bias could only be excluded by using expensive methods such as testing for cotinine (a metabolite of nicotine) in the saliva, blood or urine of the students. However, recent publications indicate that self-reports via questionnaire are relatively precise in tobacco research excluding pregnant women and patients with tobacco-related diseases [23].

Generalisation

The participants came from the two most prevalent German school types (comprehensive and grammar schools), which makes our results transferable to the majority of German students in the age group 11–15 years. The multinational programme EAT is currently enrolled in over 40 medical schools in Germany, Switzerland, Austria, Sudan, Bosnia and Herzegovina, Bangladesh and the United

States. However, as our research is not multinational, our results might not be transferable to other countries.

Conclusions

In conclusion, the EAT programme significantly reduces smoking prevalence in secondary school students at 6 months of follow-up (OR: 0.35; 95% CI: 0.15-0.78; p=0.01). Thus, medical students can effectively be involved in school-based tobacco prevention programmes. Further research and long-term evaluation is needed to confirm this *post hoc* finding.

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Protocol

The protocol of this study is freely accessed at BMJ Open [14]: http://bmjopen.bmj.com/content/4/7/e004909.full

Authors' contributions

TJB conducted the study, invented, designed and organised the intervention, wrote the manuscript, contributed to the design of the study, coordinated and conducted data entry and performed the statistical analysis. DAG contributed to the design of the study, supervised data entry and proofread the manuscript. SS-B contributed to the design of the study and the analysis of data and proofread the manuscript. WS

supported the conduction of the study and proofread the manuscript. DK supported the conduction of data entry and proofread the manuscript. All authors read and approved the final manuscript. This study is part of a thesis project (TJB).

Competing interests

The authors declare that they have no competing interests.

Funding

Each participating school paid a small fee for the copies of the questionnaire that were distributed to every participating student. This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Data sharing statement

We are not allowed to publish our full data online due to German data protection laws. The original paper based questionnaires are stored at our Institute at the Goethe-University in Frankfurt for the next ten years for documentation purposes.

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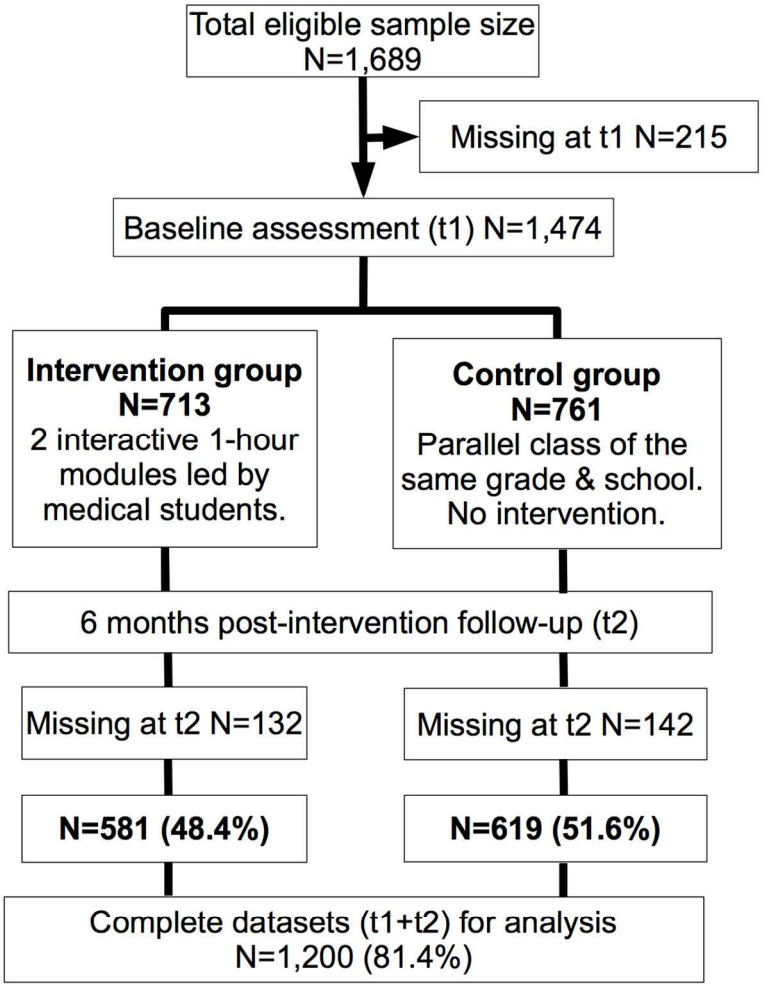

Figure 1
Study design.

209x297mm (150 x 150 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **checked**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **checked**
Objectives	3	State specific objectives, including any prespecified hypotheses **checked**
Methods		
Study design	4	Present key elements of study design early in the paper **checked**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **checked**
Participants	6	(*a*) *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls **checked**
		(*b*) *Case-control study*—For matched studies, give matching criteria and the number of controls per case **checked**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **checked**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **checked**
Bias	9	Describe any efforts to address potential sources of bias **checked**
Study size	10	Explain how the study size was arrived at **checked**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **checked**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **checked**
		(*b*) Describe any methods used to examine subgroups and interactions **checked**
		(*c*) Explain how missing data were addressed **checked**
		Case-control study—If applicable, explain how matching of cases and controls was addressed **checked**
		(*e*) Describe any sensitivity analyses **checked**

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed **cbecked**
		(b) Give reasons for non-participation at each stage **checked**
		(c) Consider use of a flow diagram **checked**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **checked**
		(b) Indicate number of participants with missing data for each variable of interest **checked**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure **checked**
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **checked**
		(*b*) Report category boundaries when continuous variables were categorized **checked**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **checked**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **checked**
Discussion		
Key results	18	Summarise key results with reference to study objectives **checked**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **checked**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **checked**
Generalisability	21	Discuss the generalisability (external validity) of the study results **checked**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **checked**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Education Against Tobacco (EAT): a quasi-experimental prospective evaluation of a multinational medical-student-delivered smoking prevention programme for secondary schools in Germany

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Education Against Tobacco (EAT): a quasi-experimental prospective evaluation of a multinational medical-student-delivered smoking prevention programme for secondary schools in Germany

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ABSTRACT

Objectives: To evaluate the multinational medical-student-delivered tobacco prevention programme for secondary schools for its effectiveness to reduce the smoking prevalence among 11-15 year olds in Germany at half year follow-up.

Setting: We used a prospective quasi-experimental study design with measurements at baseline (t1) and 6 months post-intervention (t2) to investigate an intervention in 8 German secondary schools. The participants were split into intervention- and control classes in the same schools and grades.

Participants: A total of 1,474 eligible participants of both genders at the age of 11-15 years were involved within the survey for baseline assessment of which 1,200 completed the questionnaire at six months follow-up (=longitudinal sample). The schools participated voluntarily. The inclusion criteria were age (10-15 years), grade (6-8) and school type (regular secondary schools).

Intervention: Two 60-minute school-based modules delivered by medical students.

Primary and secondary outcome measures: The primary endpoint was the difference from t1 to t2 of the smoking prevalence in the control group versus the difference from t1 to t2 in the intervention group (difference of differences approach). The percentage of former smokers and new smokers in the two groups were studied as secondary outcome measures.

Results: In the control group, the percentage of students who claimed to be smokers doubled from 4.2% (t1) to 8.1% (t2), whereas it remained almost the same in the intervention group (7.1% (t1) to 7.4% (t2); p=0.01). The chance of quitting smoking was almost six times higher in the intervention group (total of 67 smokers at

t1; 27 (4.6%) quitted in the intervention- and 7 (1.1%) in the control group; odds ratio: 5.63; 95% confidence interval: 2.01–15.79; p<0.01). However, no primary preventive effect was found.

Conclusion: We report a significant secondary preventive (smoking cessation) effect at six months follow-up. Long-term evaluation is planned.

Strengths and limitations of this study

- No medical-student-delivered school-based tobacco prevention programme has been evaluated for its preventive effect to date.
- It is imperative to sensitize prospective physicians to tobacco prevention.
- The quasi-experimental design of this study caused a selection bias due to the lack of randomization.
- As control classes were located in the same schools, cluster effects could not be excluded entirely.
- Our follow-up data was only collected six months after the intervention due to organisational reasons. Thus, we were not able to determine long-term effects.

Background

Smoking is the biggest external cause of non-contagious disease and is responsible for more deaths than obesity both globally and in high-income countries such as Germany or the USA [1, 2].

The 2011 European School Survey Project on Alcohol and Other Drugs report

revealed that a higher percentage of 16-year-old pupils from Germany claimed to have smoked in the past 30 days (33%) than pupils from Denmark (24%), Greece (21%) and Sweden (21%) [3]. Additionally, the use of water pipes has increased in the past few years in German adolescents and was described to have similarly deterious effects on human health [4, 5].

A popular school-based tobacco prevention programme, which has been implemented in many countries in the European Union, is the Smoke-free Class Competition (called “Be Smart Don’t Start”) In Germany [8-10]. However, a Cochrane systematic review from 2012 concluded that this programme was not effective for primary or secondary smoking prevention in adolescents [10].

Less popular secondary school programmes that involve physicians as health educators have already been evaluated showing significantly positive effects [6] [7]. However, they are not broadly available.

Recent studies from prestigious international and national medical faculties indicate that tobacco addiction is drastically undertreated by physicians in comparison with other chronic conditions, mainly because of lack of motivation, skills and knowledge [11-13]. Novel ways of engagement for prospective physicians was demanded [11]. A key advantage of the Education Against Tobacco (EAT) programme is that medical students learn to take tobacco-related responsibilities in their role as health educators in schools and to discuss tobacco-associated diseases in an understandable way. These aspects not only facilitate school-based prevention but also provide education for cooperative decision-making in inpatient settings [14, 15]. The multinational programme EAT is currently enrolled in over 40 medical schools in Germany, Switzerland, Austria, Uruguay, Pakistan, Sudan, Bosnia and Herzegovina,

Bangladesh and the United States.

The aim of this study was to determine the effectiveness of the school-based EAT intervention in smoking initiation prevention and smoking cessation in Germany [14]. The primary endpoint was the difference from t1 to t2 of the smoking prevalence in the intervention group versus the difference from t1 to t2 in the control group (difference of differences approach) [14]. In addition, we aimed to assess whether the programme is equally effective for participants of different gender, social and cultural backgrounds [14].

Methods

Design

As defined in our protocol, the survey was designed as a quasi-experimental prospective evaluative study with two measurements (baseline and 6 months post-intervention) [14]. The study period was October 2013 until July 2014. Participants in the two study groups (intervention and control groups) were questioned up to 2 weeks in advance of the intervention (t1) and 6 months thereafter (t2) (Figure 1).

Randomization was impossible as schools refused to participate when informed that intervention classes would be randomly externally selected. Thus, we asked the participating schools in advance to split their grades themselves into two class-groups (intervention vs. control classes) with the same performance levels (parallel classes). All intervention classes in our sample had parallel classes.

<Figure1.tiff as separate file>

Participants

A total of 1,689 eligible secondary school students from 8 eligible schools were recruited from November 2012 to October 2013. All participants fulfilled the inclusion criteria. Students aged 10 to 15 years attending grades six to eight of a secondary general, intermediate, grammar or comprehensive school were eligible [14]. Baseline data of 1,474 participants were collected from October 2013 to January 2014. Follow-up data were collected from April to July 2014. 1,200 participants provided data at both time points (t1 + t2) that was used for analysis. The loss to follow-up effect was 18.6% (N=274; intervention group: 9,0% = 132; control group: 9,6% = 142).

Attrition Analysis

The participants who dropped out at follow-up (t2) were analyzed with logistic regression analysis and showed no systematic bias with regard to the interaction between study group and smoking status (p=0.19) or study group and gender (p=0.725) or study group and school type (p=0.082). However, it showed a systematic bias for study group and age (p=0.045; OR=0.709; 95% CI: 0.51-0.99) meaning that significantly more young people dropped out of the intervention group vs. the control group.

Intervention

The intervention consisted of two interactive 60-minute modules. The first part was presented by two to six medical students and a patient with a tobacco-related disease to all pupils at the same time inside a large room within the school. It

consisted of a PowerPoint (Microsoft; Redmond, WA, USA) presentation in which the participants were encouraged to make their own well-informed decisions (social competence approach). The university hospital patient with a smoking-related disease was interviewed about his reasons for starting to smoke and the influence tobacco consumption had on his life. Again, the students were encouraged to ask the patient their own questions.

The second part took place in an interactive classroom setting in which two medical students (usually a man and a woman) tutored one class. As reported in our study protocol, both modules focused on educating adolescents about the strategies of the tobacco industry to influence their decision in a non-objective manner (social influence) and on peer pressure (social influence), decision-making and skills for coping with challenges in their life in a healthy way (social competence) [14]. The participants also discussed information relevant for their age group, e.g., why non-smokers usually look more attractive, have more money to buy things, or succeed in sports. The programme focussed on not scaring but educating its participants in an interactive manner. Accordingly, EAT used a combined social influence and social competence approach, which has been described as the most effective approach in the recently published Cochrane review [14, 16].

Data collection

We used a paper pencil survey questionnaire that was developed to collect data in the class room via the class teachers at both time points (t1 and t2) [14]. In addition to the socio-demographic data (age, gender, school type), it captured the smoking status of the school students concerning water pipe use and cigarette consumption.

The questionnaire contained numerous items that have already been included in similar investigations. The questions about the smoking status and the frequency of smoking referred to the evaluation of the school-based smoking prevention programmes in Heidelberg titled “ohne kippe” (no butts) and in Berlin titled “Students in the Hospital”, as well as to the results of the German Health Interview and Examination Survey for Children and Adolescents published by Lampert and Thamm [7, 17, 18]. As described in our study protocol, we tested and optimised the questionnaire in accordance with the Good Epidemiologic Practice guidelines [19].

The class teachers individually supervised their classes during the completion of the questionnaire. To maximise the confidentiality of the intervention, the questionnaires were placed in envelopes that were instantly sealed and co-signed by the responsible class teachers immediately after completion. The envelopes were shipped to the Goethe University of Frankfurt where they were opened and the data entry and analysis was performed under the supervision of two of the authors (DAG and DK).

Outcomes

The primary endpoint was the difference from t1 to t2 of the smoking prevalence in the control group versus the difference from t1 to t2 in the intervention group (difference of differences approach). The percentage of former smokers and new smokers in the two groups were studied as secondary outcome measures. A smoker was defined as a pupil who claimed to smoke at least “once a month” within the survey. Non-smokers are defined as pupils who claimed to smoke less than “once a month” within the survey. The pupils who claimed not to smoke at all were defined as non-smokers.

Statistical analysis

Analysis

To examine baseline differences we used χ^2-tests (categorical variables) and t-tests (continuous variables). The effects of predictors (gender, culture and social characteristics) of smoking cessation were calculated by robust panel logistic regression analysis. The significance level was 5% for t-tests (double-sided) and 95% for confidence intervals (double-sided). Statistical analysis was performed using SPSS Statistics Version 23 by IBM (Armong, USA) and STATA 14 by StataCorp (Texas, USA). In our sample the group allocation was not on the individual level but on the class level. In order to take into account this clustering statistically we used robust panel logistic regression (xtlogit proceduce with vce (cluster) option). This procedure was also used to calculate the difference from t1 to t2 of the smoking prevalence in the control group versus the difference from t1 to t2 in the intervention group (our primary endpoint) by the help of STATA 14 by StataCorp (Texas, USA).

Legal approval

In accordance with Good Epidemiologic Practice guidelines, an ethics waiver and all legal permissions were obtained from the responsible institutions before data collection started as described in our study protocol [14, 19].

Results

Baseline data

The median age of the 1,474 eligible participants at baseline (Fig. 1) was 13 years (mean age 12.55 years; range 11–15 years) and 52.0% were female. Of the

participants, 43.9% attended grammar schools and the remaining 56.1% attended comprehensive schools (which were classified in the survey as “lower education level”). The survey identified 6.4% of participants as smokers at baseline. There were no significant differences concerning the number of smokers in both groups (p=0.088; Table 1).

Table 1: Descriptive data at baseline

Variables	Intervention group (N=713)	Control group (N=761)	P-Value
Gender (n) (%) • Male • Female	 349 (49.5) 356 (50.5)	 352 (46.6) 404 (53.4)	 0.261
Age • Mean (±SD)	 12.47 (0.79)	 12.64 (0.78)	 <0.01
Schooltype (n) (%) • Grammar • Comprehensive	 281 (39.4) 432 (60.6)	 366 (48.1) 395 (51.9)	 <0.01/ 0.046[a]
Migrant BG (n) (%)	182 (27.5)	221 (31.3)	0.122
Smoking status (n) (%) Smokers Non Smokers	 54 (7.6) 659 (92.4)	 41 (5.4) 720 (94.6)	 0.088
Smoking behaviour of non-smokers, (n) (%) Never smoked Stopped less than 6 months beforehand Stopped more than 6 months beforehand	 615 (95.1) 9 (1.4) 23 (3.6)	 683 (97.0) 12 (1.7) 9 (1.3)	 0.021
Smoking behaviour of smokers (n) (%) *Cigarettes (monthly-daily)* Daily More than once per week	 32 (60.4) 8 (25.0)	 21 (39.6) 4 (19.1)	 0.435 0.613

Once per week	2 (6.3)	2 (9.5)	0.659
Monthly	4 (12.5)	3 (14.3)	0.851
	18 (56.3)	12 (57.1)	0.683
Waterpipe-smokers (monthly-daily)	34 (58.6)	24 (41.4)	0.661
Daily	3 (8.8)	0 (0)	0.135
More than once per week	6 (17.7)	3 (12.5)	0.594
Once per week	5 (14.7)	2 (8.3)	0.463
Monthly	20 (58.8)	19 (79.2)	0.104

a) p-value adjusted for class size (classes in the intervention group were systematically smaller than in the control group (mean class size = 23.96 vs. 25.07 in control group; p<0.01))

Follow-up at 6 months

Analyses of the data were by original assigned groups: There were 581 pupils in the intervention group and 619 pupils in the control group who had participated in the survey at both time points (baseline sample=1,474; prospective sample=1,200 pupils; loss to follow-up=274 pupils).

Primary Endpoint

There was a significant effect for the defined primary endpoint (OR: 0.35; 95% CI: 0.15-0.78; p=0.01) calculated with the prospective sample of 1,200 participants (Table 2): The percentage of students who claimed to be smokers doubled from 4.2% (t1) to 8.1% (t2) in the control group, whereas it remained almost the same in the intervention group (7.1% (t1) to 7.4% (t2)). The development in terms of smoking prevalence of the two study groups was significantly different (p=0.01; Table 2).

Table 2: Primary endpoint calculated by robust panel logistic regression (xtlogit proceduce with vce (cluster) option)

Variable	Standard Error	P-Value	Odds Ratio	95% Confidence Interval	
				Lower	Upper
time#group#endline#intervention group*	0.14	0.01	0.35	0.15	0.78

* Difference in smoking prevalence from t1 to t2 of the smoking prevalence in the control group versus the difference from t1 to t2 in the intervention group (see methods section).

Secondary Outcomes

At six months follow up, 27 (4.6%) smokers in the intervention group had quitted but only 7 (1.1%) smokers in the control group were abstinent (Table 3). However, no primary preventive (initiation prevention) effect was found as in both groups 5.0% of the prospective sample started to smoke (Table 3).

Table 3: Nominal and percentage effects of the intervention on the smoking status (secondary outcomes)

		Prospective smoking status (t1-t2)			
		stays nonsmoker	starts smoking	stops smoking	stays smoker
control group	N	562	31	7	19
	% in group	90.8%	5.0%	1.1%	3.1%
intervention group	N	511	29	27	14
	% in group	88.0%	5.0%	4.6%	2.4%
Total	N	1073	60	34	33
	% in group	89.4%	5.0%	2.8%	2.8%

Predictors of smoking cessation

The chance of quitting smoking was more than five times higher in the intervention group according to robust panel logistic regression analysis (OR: 5.63; 95% CI: 2.01–15.79; p<0.01; Table 4. As can also be seen in Table 4, age seems to have a significant effect on smoking status: increasing the age by 1 year within our sample (11–15 years) reduces the chance to stop smoking by 61% (OR: 0.39; 95% CI: 0.19–0.78). Students from comprehensive school within our prospective sample have a 60% lower chance of quitting smoking when compared with students from grammar schools (OR: 0.40; 95% CI: 0.18-0.91; p=0.03).

Because the sample sizes for smokers in the intervention group were relatively small, we cannot prove a systematic co-dependency between quitting smoking and migrant background or gender.

Table 4: Robust panel logistic regression analysis (main effects) for prediction of quitting smoking by smokers (n=67)

Variables	Robust Standard Error	P-Value	Odds Ratio	95% Confidence Interval	
				Lower	Upper
Age	0.14	<0.01	0.39	0.19	0.78
Gender (ref. female)	0.74	0.64	1.31	0.43	3.98
Intervention group (ref. Control)	2.96	<0.01	5.63	2.01	15.79
Comprehensive school (Ref. Grammar school)	0.17	0.03	0.40	0.18	0.91

Discussion

School-based physician-delivered tobacco prevention programmes have shown short-term and long-term effectiveness but are usually expensive and tutor relatively few students [6, 7, 20]. At the same time, it is imperative to sensitise prospective physicians to tobacco addiction and associated responsibilities within communities [21, 22]. In this study, we report a significant effect to reduce smoking prevalence of a widespread intervention delivered by volunteer medical students to secondary school students (11–15 years); at 6 months of follow-up, the odds ratio was 5.63 to stop smoking in the intervention vs. the control group (CI: 2.01–15.79; p<0.01). To the best of our knowledge, this study is the first evaluation of a medical student-delivered school-based tobacco intervention.

Interpretation

Our data reveal that motivating students to quit smoking using EAT works significantly better at a young age (p<0.01), which suggests that younger smokers are not as addicted as older smokers but are more likely to be in the phase of experimentation. In accordance, most of the smoking participants in the survey claimed to smoke less than once a day. The participants who started smoking also showed experimentation characteristics (most of them smoking less than once a day). Thus, we hypothesise that in this young age group it may be more difficult to reduce curiosity and to avoid experimentation behaviour in the short-term than it is to convince those who have already experimented with cigarettes to stop smoking. This thesis is supported by numerous publications addressing this age group, which show no primary preventive effect at half year follow-up with various approaches [16]. Another explanation for the short-term result of no primary prevention effect can be found within the recent Cochrane review: Combined social competence and social

influence programmes such as EAT did not show primary preventive effectiveness at less than 1 year follow-up within the meta analysis [16]. Thus, our intervention might also show a primary preventive effect at longer follow-up. In addition, we hypothesize that the effect on reducing smoking prevalence in the intervention group would have been larger in a randomised experimental setting as we found two biases both potentially shrinking the effect of the intervention (see below).

The implementation of cost-effective measures to prevent smoking in adolescents and, moreover, the sensitisation of prospective physicians to tobacco-attributable diseases, tobacco prevention, and improved communication of these issues in medicine is addressed by our programme [11-13, 15].

Limitations

Our data indicate that the quasi-experimental design of our study caused some selection bias as the number of smokers (7.6% vs. 5.4%) and former smokers (5% vs. 3%) was higher in the intervention group in the complete baseline sample (cross sectional data). The teachers probably insisted on choosing classes at higher risk for smoking as intervention classes which is also illustrated by a significant higher number of pupils visiting classes with a lower education level within the intervention group ($p<0.01$) as smoking correlates with low education [6]. Accordingly, our robust panel logistic regression analysis on our prospective smoker subgroup revealed that students from comprehensive schools have a significantly lower chance to quit smoking ($p=0.03$). As young age is also a significant predictor of quitting in our sample ($p<0.01$), the reported attrition bias showing that systematically more young students dropped out in our intervention group ($p=0.045$) might have lowered the effect of the intervention. Thus, we report two systemic biases in our quasi-

experimental design considering age (attrition bias; p=0.045) and school type (selection bias; significantly more comprehensive school students and less grammar school students in our intervention group at baseline; p<0.01) which both rather decrease the measured effect in reducing smoking prevalence of the intervention. In addition, cluster effects could not be excluded, because the intervention and control groups attended the same schools.

Our study relies on self-reports obtained from adolescents via questionnaire; therefore, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, possibly because of social desirability bias. This bias could only be excluded by using expensive methods such as testing for cotinine (a metabolite of nicotine) in the saliva, blood or urine of the students. However, recent publications indicate that self-reports via questionnaire are relatively precise in tobacco research excluding pregnant women and patients with tobacco-related diseases [23].

Generalisation

The participants came from the two most prevalent German school types (comprehensive and grammar schools), which makes our results transferable to the majority of German students in the age group 11–15 years. However, as our research is not multinational, our results might not be transferable to other countries.

Dissemination of the intervention

About 3 years after medical student Titus J. Brinker founded EAT (January 2012), the programme has more participating mentors (800 medical students) and interactively educates more secondary school students (20,000) per year than any

other known school-based physician-delivered or medical-student-delivered tobacco prevention programme in Germany or, as far we know, worldwide. It is enrolled in over 40 medical schools in Germany, Switzerland, Austria, Uruguay, Pakistan, Sudan, Bosnia and Herzegovina, Bangladesh and the United States. It currently costs about EUR 20 per participating class and is therefore less expensive than comparable programmes.

Conclusions

In conclusion, the EAT programme significantly reduces smoking prevalence in secondary school students at 6 months of follow-up (OR: 0.35; 95% CI: 0.15-0.78; p=0.01). Thus, medical students can effectively be involved in school-based tobacco prevention programmes. Further research and long-term evaluation is needed to confirm this *post hoc* finding.

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Protocol

The protocol of this study is freely accessed at BMJ Open [14]: http://bmjopen.bmj.com/content/4/7/e004909.full

Authors' contributions

TJB conducted the study, invented, designed and organised the intervention, wrote the manuscript, contributed to the design of the study, coordinated and conducted data entry and performed the statistical analysis. DAG contributed to the design of the study, monitored data entry and proofread the manuscript. SS-B contributed to the design of the study and the analysis of data and proofread the manuscript. WS supported the conduction of the study and proofread the manuscript. DK supported the conduction of data entry and proofread the manuscript. All authors read and approved the final manuscript. This study is part of a thesis project (TJB).

Competing interests

The authors declare that they have no competing interests.

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Data sharing statement

No additional data available.

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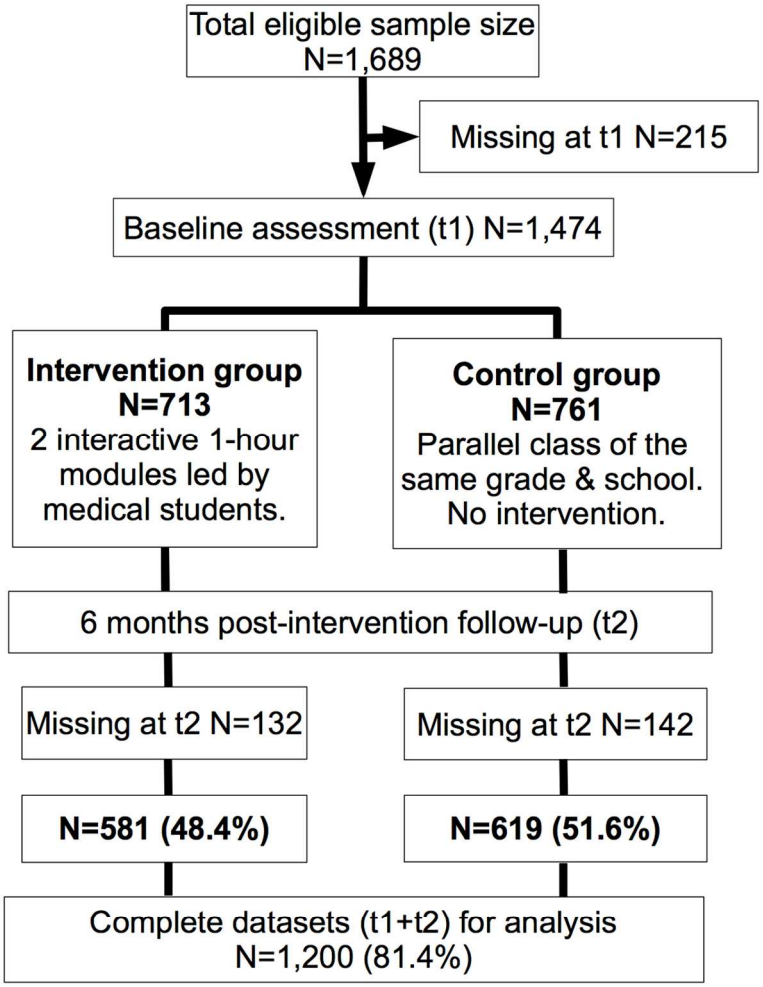

Figure 1
Study design.

209x297mm (150 x 150 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **checked**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **checked**
Objectives	3	State specific objectives, including any prespecified hypotheses **checked**
Methods		
Study design	4	Present key elements of study design early in the paper **checked**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **checked**
Participants	6	(*a*) *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls **checked**
		(*b*) *Case-control study*—For matched studies, give matching criteria and the number of controls per case **checked**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **checked**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **checked**
Bias	9	Describe any efforts to address potential sources of bias **checked**
Study size	10	Explain how the study size was arrived at **checked**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **checked**
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **checked**
		(*b*) Describe any methods used to examine subgroups and interactions **checked**
		(*c*) Explain how missing data were addressed **checked**
		Case-control study—If applicable, explain how matching of cases and controls was addressed **checked**
		(*e*) Describe any sensitivity analyses **checked**

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed **cbecked**
		(b) Give reasons for non-participation at each stage **checked**
		(c) Consider use of a flow diagram **checked**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **checked**
		(b) Indicate number of participants with missing data for each variable of interest **checked**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure **checked**
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **checked**
		(*b*) Report category boundaries when continuous variables were categorized **checked**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **checked**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **checked**
Discussion		
Key results	18	Summarise key results with reference to study objectives **checked**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **checked**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **checked**
Generalisability	21	Discuss the generalisability (external validity) of the study results **checked**
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **checked**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.