Education Against Tobacco (EAT) - Evaluation of a school-based program for preventing smoking delivered by medical students: a study protocol

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Education Against Tobacco (EAT) - Evaluation of a school-based program for preventing smoking delivered by medical students: a study protocol

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ABSTRACT

Background: In a survey conducted and published by the Federal Centre for Health Education in Germany in 2012 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) described themselves as regular cigarette smokers. Most smokers have consumed their first cigarettes in early adolescence. We recently reported a significantly positive short-term effect of a school-based smoking prevention program on the smoking behaviour of school children delivered by physicians in Germany. Since physician-based programs are usually very expensive, we aim to evaluate and optimize the widespread low-cost program "education against tobacco" which is being delivered by about 400 medical students at 16 universities in Germany.

Methods/Design: We perform a prospective case-control study with quasi-experimental design among 10 to 15-year old children of secondary schools in Germany visiting school grades six to eight. The intervention program consists of two medical-student delivered modules within the schools of about 60 minutes duration each. The first module also involves patients with tobacco related diseases. The control group does not receive any intervention.

To collect the data, we designed and pre-tested a questionnaire measuring the smoking status (water pipe and cigarette smoking), smoking-related cognitions as well as gender, social, and cultural aspects. Data will be collected at baseline and six months post the intervention.

Discussion: This study protocol describes the design of a prospective case-control study that will evaluate the effectiveness of a school-based smoking prevention program delivered by medical students. We expect that a significantly lower number of children will start smoking in the intervention group compared to the control group

as a direct result of this intervention. We will optimize the curriculum on the basis of the results of this evaluation to make it optimally effective for both genders and different ethnic groups.

Strengths and limitations of this study

A consequence of our research is suspected to be the general acceptance that medical students and even more medical interns (PJ-medical students) offer a great opportunity to deliver prevention programs. Therefore, health systems worldwide may largely benefit from the development of a novel and low-cost measure of primary prevention. A main limitation would be the fact that our research is not been done multinationally and therefore might not be representative for every ethnical and cultural background. Futhermore, the case and the control groups were in the same schools which is a potential confounding variable as the pupils could exchange what they have learned about smoking due to the intervention during the school breaks.

Keywords: smoking prevention, school-based prevention, primary prevention, medical students, schools, adolescents

Background

Tobacco consumption is a risk factor for various diseases and leads to the highest number of avoidable deaths worldwide [1]. Despite warning labels and public interventions, smoking causes diseases and death in Germany where it was responsible for almost 107.000 deaths in 2007 [2, 3]. In addition, it generates high financial costs. A study which modelled the costs of productivity losses due to smoking in Germany for the year 2005 [3] calculated productivity costs of 9.6 billion

Euro which were caused by smoking. Most smokers started smoking in early adolescence [4]. In a survey conducted and published by the Federal Centre for Health Education (Bundeszentrale für gesundheitliche Aufklärung, BZgA) in Germany in 2012 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) described themselves as regular cigarette smokers [5]. Furthermore, in the past few years there was an increase in the use of water pipes [6]. According to a survey conducted by the Federal Centre for Health Education in 2011, 8.7% of adolescents and 11.2% of the participating young adults had smoked water pipe at least once in the 30 days leading up to the survey [6]. Male respondents have smoked water pipe more frequently than women [6]. According to Maziak, water pipes lead the way to cigarette smoking and have similarly deleterious effects for human health [7].

A survey conducted in 2006 quantified nicotine dependency with the help of the Fagerström test [8]. It reported that 50.8% of the 15– to 17-year-old smokers and 41.8% of those in the 18– to 24-year age group were dependent on nicotine. Laucht and Schmid reported a correlation between the number of cigarettes smoked and the starting age in 15-year-old adolescents [9]. It was demonstrated that the earlier in life they had smoked their first cigarette, the more likely they were still consuming tobacco, the more cigarettes they were currently consuming and the higher was their degree of dependence.

Early primary prevention of smoking is thus of crucial importance and therefore should be promoted, evaluated and optimized.

School-based smoking prevention program

The registered association „education against tobacco“ (hereinafter referred to as "EAT") has been founded and developed since August 2011 by medical student Titus Brinker of the University of Gießen in cooperation with professors from the Universities of Gießen, Frankfurt and Marburg as well as fellow students from the Texas A&M University. The program has been developed taking into account the Cochrane Database Systematic Review on school-based programmes for preventing smoking (2006)(13) in regard of its conclusion to focus on the development of low cost prevention programs and its implication for research to combine social influences approaches with generic social competence approaches. Both of these key points have been taken into account when developing the EAT curriculum. At the time of development there was already research available which encouraged EAT to use medical students as Sussman et al [10] concluded that health educator-led drug prevention programs are more effective than self-instructed programs.

Since physician-based programs have proven to be successful [12] but usually are very expensive, we aim to evaluate and optimize the widespread low-cost program “education against tobacco“ which is being delivered by about 400 medical students at 16 universities in Germany. The city of Gießen provides an excellent platform to evaluate this effect as it homes the largest EAT group with the highest experience level and the most participating EAT schools.

Objectives

In the past years, prevention science has emerged as a research discipline built on the integration of life course development research, community epidemiology, and preventive intervention trials. Our objective is to integrate these aspects in order to

promote prevention in the area of tobacco addiction with a focus on low cost widespread programs.

We plan to evaluate the effect on the smoking behavior of the curriculum being delivered by medical students in order to reach a sound basis for a future, nation-wide program. In this connection, we consider gender, social, and cultural aspects of the intervention in order to optimize the curriculum which includes the design of an evidence-based and easy to implement train the trainer EAT program as a consequence of this study by engulfing recent research knowledge on smoking related diseases. By doing this, we plan to improve the education of the health educators (participating medical students) by the use of additional expert knowledge on the topic. This train the trainer program also sensitizes the medical students – regardless of their future medical specialization – towards the needs of tobacco prevention and thus increases the knowledge on prevention among the future physicians.

Consequently, it is our strategy to perpetuate the program on a national level by developing a system for the integration of EAT into the structure of medical faculties and large teaching hospitals. In this respect, we will customize the project for an integration of EAT into elective courses (Wahlfächer) or cross sectional areas (Querschnittsbereiche) such as prevention (QB10) or environmental medicine (QB6) at the medical schools of the 16 EAT partner universities.

Methods

Study design and setting

The survey will be designed as a prospective case-control study with quasi-experimental design. We could not afford randomization as it includes a huge organizational and personal effort we were not capable to perform. In addition, some classes would not agree to participate within the study when they would be predetermined as control groups which became clear in advance of the investigation. To keep confounding factors to a minimum, the parallel class of intervention classes in a given grade is selected for the control group. To maximize the external validity of the intervention, the questionnaires will be put into envelopes which are instantly being sealed by the responsible class teachers after completion. The teachers sign a brief declaration where they state to be fully responsible for the sealing process directly after the questionnaires have been filled out by the pupils. The envelopes will be opened and the data evaluation will be performed under the supervision of Prof. Dr. Groneberg at the Goethe University Frankfurt. The class teachers individually supervise their classes for the completion of the questionnaire.

For the collection of the data we will use a written survey in the form of a questionnaire. This questionnaire is developed to collect data to each of the defined time points (t1-t2). In addition to the socio-demographic data (age, gender, school type), we will obtain the smoking status of the school students concerning water pipe and cigarettes.

The questionnaire will contain numerous items which have already been a part of similiar investigations. The questions about the smoking status and the frequency of smoking refer to the evaluation of the school-based smoking prevention program from Heidelberg „ohne Kippe“ [13] and the publication of Lampert and Thamm [14] about the results of the child and adolescent surveys (KiGGS).

The period of time of the survey is planned to be from October 2013 until July of 2014. Participants in two study groups (intervention by medical students and control) will be questioned up to 2 weeks in advance of the intervention (t1) and 6 months thereafter (t2) (see Figure 1).

To test the questionnaire in accordance to the GEP guidelines [15], we carried out 88 copies to pupils with the lowest education level participating in May 2013. We investigated that 85 of these questionnaires were filled out in a useful way for evaluation. However, seven pupils did not fill out the questionnaire completely. We added a notification to turn the page at the bottom of each page to fix this problem.

Participants and Sample Size

Eligibility criteria

Students aged 10 to 15 attending a secondary general, intermediate, grammar, or comprehensive school are eligible. The schools in Gießen and the surrounding cities are already involved in the program and let their classes participate every year. Participation is voluntary and could be ended at any time without giving a reason.

Legal approval

In accordance to Good Epidemiologic Practice (GEP) guidelines[15], approval of the responsible ethics committee was asked for and the committee decided that the study does not need ethical approval (ethics committee of the Goethe University, Frankfurt am Main, Germany). All legal preparations and data protection issues have been discussed with the responsible ministry of education and cultural affairs in Germany. The ministry gave approval for the stated proceed of data collection within the participating schools. In addition, each school individually discussed and

approved the study in its schools' conference. The participation of each student was declared to be voluntarily and informed written consent was obtained from the parents of the study participants.

Sample Size Calculation

The recruitment sample was calculated on the basis of a recently published study [12] and will amount to 1.002 pupils (n1 = 501 participating in the medical students delivered intervention n2 = 501 pupils in the control group) at least at a test power of 80% (alpha = 0,05). In consideration of the loss to follow-up effect, it is planned to include at least 1.200 participants (600 per group).

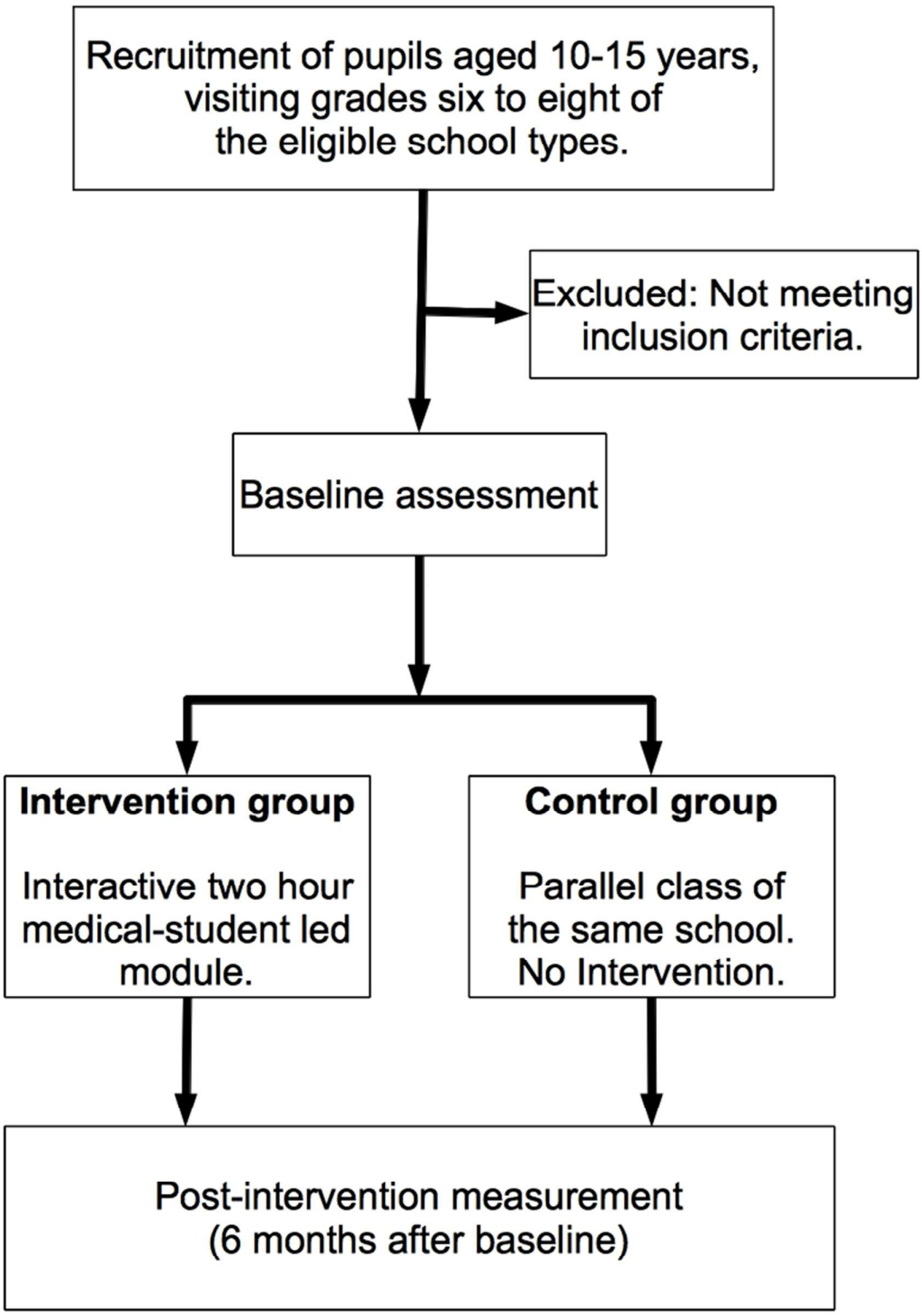

Figure 1
Study design.

Intervention

The intervention consists of two parts of 60 minutes duration each. The first part is delivered in a large room in front of all pupils of the grade including a patient with a tobacco related disease talking about his own experiences with tobacco addiction and an information giving power point presentation. The second session is performed in an interactive classroom setting with two medical students mentoring one class. In advance of the school visit, the medical students receive brief didactic instructions, information on tobacco addiction and FAQs for preparation and a detailed plan of the curriculum. The EAT program uses a combined information giving, social competences and social influences approach.

Gender specific aspects

According to our recent study using the physician-based approach for school-based tobacco prevention [12], girls benefit from physician-delivered programs more than boys (OR 2.56, CI 1.06–6.19). We aim to assess if this result is also obtained using the EAT medical student-based approach to address gender-specific aspects. As a consequence, the program then needs to be modified for gender mainstreaming since both sexes need to be addressed equally.

Cultural aspects

We hypothesize a small but significant relation between water pipe smoking and the cultural background of the pupils since tobacco smoking using a water pipe is traditional in the region of the Middle East [16]. Therefore, we plan to collect data about the cultural background. With regard to this hypothesis, comprehensive information about water pipe smoking is an integrative element of the EAT

curriculum. Within the projected optimization process, the EAT curriculum can also be structured in relation to the different school populations which can be encountered (i.e. schools with a high percentage of pupils of migration background vs. schools without).

Social aspects

According to a survey conducted by the Federal Centre for Health Education [5], the prevalence of cigarette smoking in the age group of 10 to 15 year old pupils was significantly higher in schools with lower education levels in Germany in 2012 (16,7% vs. 6,9%)(16). As a consequence, we plan to specifically address schools with lower education levels and to compare the effects on different school types.

Outcomes

The primary endpoint is the percentage difference between smokers and non-smokers in the two study arms at baseline and 6 months after the intervention (lifetime prevalence). Measures of smoking behavior (the number of cigarettes and water pipes smoked) will be studied as secondary outcome measures.

Statistical analysis

In order to determine relevant effect sizes in consideration of the measurements before and after the intervention, we plan to use the χ^2-square-test for frequency distributions. In addition, we plan to use the t-Test/the Wilcoxon-test for mean value differences of paired and unpaired samples. In order to illustrate the attitude towards smoking between the intervention groups and the control group during the time progress of the study we plan to use the univariate variance analysis. For the calculation of the predictors of the smoking behavior we use the logistic regression

analysis which is the state-of-the-art technique for the evaluation of the effectiveness of prevention programs [13, 17, 18].

The test for significance is planned on the 5% level (double-sided), confidence intervals for 95% (double-sided). The software for our analysis is planned to be the newest version of SPSS Statistics for Mac by IBM.

Discussion

So far, medical student delivered school-based programmes for preventing smoking have not been evaluated. Therefore, only little relevant data is available in scientific databases such as Medline or PubMed. The most relevant publication on the topic is the Cochrane Database Analysis on school-based programs for preventing smoking [19]. The authors analyzed the data from 134 studies, in 25 different countries, which included a total of 428.293 young people aged 5-18. Of these, 49 studies reported smoking behavior in those adolescents who had never previously smoked. The authors concluded that further research is required to design and test programs that will be equally effective for both genders, different cultural backgrounds and ethnic groups. Interventions delivered by adult educators were shown to be more effective in the longer term than peer-education programs. In this respect, medical students belong to the group of adult educators. According to the Cochrane Analysis, cost-effectiveness plays an important role for practical implementation. As EAT is delivered by volunteering medical students, it is less expensive but more available than physician delivered programs.

The Cochrane Database Analysis did not include recently published data on school-based health educator delivered programs in Germany. Within the evaluation of the physician-based program ”Students in the Hospital” in Berlin, significant positive results were present for an information-based curriculum [12].

An anonymous survey by questionnaire from September 2007 to July 2008 was conducted, with a quasi-experimental control-group design, two weeks before (t1) and six months after (t2) the intervention in a group of 760 participating school students in Berlin.

The results indicated that 40.8% of the participants were smokers, among whom 79% stated that they also smoked water pipes. As major primary prevention outcome of the study, it was found that significantly fewer students in the intervention group than in the control group began smoking in the six months after the intervention ($p<0.001$). In addition, the chance of remaining a non-smoker was four times as high in the intervention group (OR, 4.14; CI, 1.66–10.36). Concerning gender aspects, girls appeared to benefit more from the intervention than boys (OR 2.56, CI 1.06–6.19)(1). 16.1% of smokers in the intervention group and 17.6% in the control group stopped smoking ($p>0.05$). Conclusively, a clear primary preventive effect of the program was demonstrated.

Since physician-based programmes are usually very expensive, it is indicated to evaluate a less expensive and widespread program.

Conclusion

A consequence of our research is suspected to be the general acceptance that medical students and even more medical interns (PJ-medical students) offer a great opportunity to deliver primary prevention programs. This does not only refer to inpatient secondary prevention but especially refers to primary prevention within the community/school. Therefore, the German health system may largely benefit from the development of a novel and low-cost measure of primary prevention.

Authors' contributions:

TJB participated in the design of the study, carries out the study, drafted the manuscript and is supposed to perform the statistical analysis. WS supports the coordination of the study. SS-B participated in the design of the study, participated in the writing process and corrected the manuscript. DAG participated in the design of the study and corrected the manuscript. All authors read and approved the final manuscript.

Competing interests:

The authors declare that they have no competing interests.

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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.

BMJ Open

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ABSTRACT

Background: A survey conducted by the German Federal Centre for Health Education in 2012 showed that 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) in Germany are regular cigarette smokers. Most consumed their first cigarette in early adolescence. We recently reported a significantly positive short-term effect of a physician-delivered school-based smoking prevention programme on the smoking behaviour of school children in Germany. However, physician-based programmes are usually very expensive. Therefore, we will evaluate and optimize Education against Tobacco (EAT), a widespread, low-cost programme delivered by about 400 medical students from 16 universities in Germany.

Methods and analysis: Prospective quasi-experimental study design with two measurements at baseline (t1) and 6 months post-intervention (t2) to investigate an intervention in 10- to 15-year-olds in grades six to eight at German secondary schools. The intervention programme consists of two 60-minute school-based medical-student delivered modules with (module 1) and without the involvement of patients with tobacco-related diseases and control groups (no intervention). The study questionnaire measuring smoking status (water pipe and cigarette smoking), smoking-related cognitions, and gender, social and cultural aspects was designed and pre-tested in advance. The primary endpoint is the percentage difference between smokers and non-smokers in the two study arms at baseline and 6 months after the intervention. The percentage of former smokers and new smokers in the two groups and the measures of smoking behaviour will be studied as secondary outcome measures.

Ethics and dissemination: In accordance with Good Epidemiologic Practice (GEP) guidelines, the study protocol was submitted for approval by the responsible ethics committee, which decided that the study does not need ethical approval (Goethe University, Frankfurt-Main, Germany). Findings will be disseminated in peer-reviewed journals, at conferences, within our scientific advisory board and through medical students within the EAT project.

Strengths and limitations of this study

- No medical student-delivered school-based tobacco prevention programme has been evaluated for its primary preventive effect to date.
- It is imperative to sensitize prospective physicians to tobacco prevention.
- The quasi-experimental design of this study might cause a selection bias due to the lack of randomization.
- Cluster effects cannot be excluded entirely as the control classes are located in the same schools and pupils could exchange what they have learned.
- As our research is not multi-national, it might not be useful for persons of all ethnic and cultural backgrounds.
- Because our study relies on self-reports obtained from adolescents via a questionnaire for data collection, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, e.g. due to social desirability bias.
- Our follow-up data is only collected six months after the intervention due to organisational reasons. Thus, we will not be able to determine which effects the intervention might have at one year follow-up.

Background

Tobacco consumption is a risk factor for various diseases and leads to the highest number of avoidable deaths worldwide [1]. Despite warning labels and public interventions, smoking was responsible for almost 107,000 deaths in Germany alone in 2007 [2]. There are high costs associated with smoking. One study estimated the smoking-related costs for acute hospital care, inpatient rehabilitation care, ambulatory care and prescription drugs in Germany to be EUR 7.5 billion in 2003 [3].

Most smokers started smoking in early adolescence [4]. In a survey conducted by the German Federal Centre for Health Education (BZgA) in 2012, 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) in Germany described themselves as regular cigarette smokers [5]. A 2006 survey that quantified nicotine dependence in Germany using the Fagerström test [6] reported that 50.8% of the 15- to 17-year-old smokers and 41.8% of the 18- to 24-year-old smokers were dependent on nicotine. Laucht and Schmid [7] reported a correlation between the number of cigarettes smoked by 15-year-olds and the starting age of smoking; moreover, those adolescents who had started smoking earlier in life were more likely to be still consuming tobacco and to consume more cigarettes and have a higher degree of dependence than their peers.

Furthermore, the use of water pipes has increased in the past few years [8]. According to a 2011 survey by the Federal Centre for Health Education, 8.7% of adolescents and 11.2% of young adults surveyed had smoked water pipe at least once in the 30 days leading up to the survey [8]. Male respondents smoked water pipe more frequently than women [8]. According to Maziak, water pipes lead the way to cigarette smoking and have similarly deleterious effects on human health [9]. Early primary prevention of smoking is thus of crucial importance and should be promoted,

evaluated and optimized.

Some scientifically validated smoking prevention programmes already exist in Germany, like the Smoke-Free Class (SFC) competition, which was shown to have a significant primary preventive long-term effect and cost-effectiveness [10, 11]. However, the SFC competition focuses only on cigarettes and not on water pipe smoking. In addition, there is no comparable beneficial effect for the instructors of the SFC programme. Education Against Tobacco additionally sensitizes prospective physicians to the importance of tobacco prevention. A recent study from Yale University suggests that tobacco addiction is undertreated by physicians in comparison to other chronic conditions [12]. The authors concluded that alternative models of engagement may be needed to enhance use of effective treatments for tobacco addiction and to raise awareness among physicians.

To our knowledge, medical student delivered school-based programmes for preventing smoking have not been evaluated to date. Little relevant data is available in scientific databases such as Medline or PubMed. The most relevant publication on the topic is the Cochrane Database Analysis on school-based programmes for preventing smoking [13]. The authors analyzed the data from 134 studies in 25 different countries in a total of 428,293 young people aged 5 to 18. Forty-nine of these studies reported smoking behaviour in adolescents who had never previously smoked. No overall effect of intervention curricula vs. control was found based on the pooled results at follow-up at one year or less (odds ratio [OR] 0.94, 95% confidence interval [CI] 0.85 to 1.05) [13]. From our perspective, the most relevant finding of the Cochrane Analysis is that social competence and social influence curricula have a statistically significant effect of preventing the onset of smoking [13]. The authors concluded that further research is required to design and test programmes that will

be equally effective for people of different genders, cultural backgrounds and ethnic groups. Interventions delivered by adult educators were shown to be more effective in the longer term than peer-education programmes. Medical students belong to the group of adult educators. According to the Cochrane Analysis, cost-effectiveness plays an important role in practical implementation. As Education against Tobacco is delivered by medical student volunteers, it is less expensive and more available than physician-delivered programmes.

Secondary school programmes which involve physicians as health educators already exist. In fact, Stamm-Balderjahn et al. [14] recently published data on a school-based physician-delivered programme (Students in the Hospital) in Berlin, which achieved significant positive results with a multimodal approach .From September 2007 to July 2008, they conducted an anonymous questionnaire survey with a quasi-experimental control group design two weeks before (t1) and six months after (t2) the intervention in a group of 760 participating school students in Berlin. The results indicated that 40.8% of the participants were smokers at baseline, 79% of whom stated that they also smoked water pipes. Regarding the primary prevention outcome of the study, it was found that significantly fewer students in the intervention group began smoking within six months of the intervention than in the control group ($p<0.001$). In addition, the chance of remaining a non-smoker was four times higher in the intervention group (OR, 4.14; CI, 1.66–10.36). Concerning gender, girls appeared to benefit more from the intervention than boys (OR 2.56, CI 1.06–6.19). 16.1% of smokers in the intervention group and 17.6% in the control group stopped smoking ($p>0.05$). A primary preventive effect of the programme was clearly and conclusively demonstrated.

Non-smoking is Cool (NiC), another physician-delivered programme based in

Hamburg, Germany, addresses grades 5 to 6 of all secondary school types (total sample size reported: 1359 students) [15]. The programme uses a social influence- and fear-based curriculum. Multiple studies have shown that fear-based appeals are ineffective for primary tobacco prevention in the long term [16]. NiC proved to be effective in grammar schools, where it reduced the onset of smoking in the intervention group by 50% compared to the control group at three and nine months follow-up, but with a small effect size [17]. Nevertheless, it failed to show a significant primary preventive effect in schools with a lower educational level (general, intermediate, or comprehensive school) [17].

Considering the high cost of physician-based programmes and the lack of available physicians, it is indicated to evaluate a less expensive and widespread programme that sensitizes prospective physicians to tobacco prevention.

School-based smoking prevention programme delivered by medical students

Education Against Tobacco (EAT) is a non-profit, medical student-delivered school-based smoking prevention programme founded in August 2011 by Titus Brinker, a medical student at the University of Gießen, and developed in cooperation with professors from the Universities of Gießen, Frankfurt and Marburg as well as medical students from Texas A&M University. The programme takes the Cochrane Analysis into account [18]. Its mission is to focus on the development of low-cost prevention programmes and their implications for research, and to combine social influences approaches with generic social competence approaches. Both of these key points were taken into account when developing the curriculum. At the time of development, there was already research available that encouraged the use of medical students in such programmes. For example, Sussman et al. [19] concluded that health educator-led drug prevention programmes are more effective than self-instructed programmes.

Since physician-based programmes have proven to be successful [14] but usually are very expensive, we aimed to evaluate and optimize Education Against Tobacco, a widespread low-cost programme which is being delivered by about 400 medical students at 16 universities in Germany. It costs only about EUR 25 per participating class. The city of Gießen, home of the largest EAT group with the highest level of experience and the most participating EAT schools, is an adequate platform to evaluate the effects of EAT.

Objectives

1) To assess the efficacy of the programme, we investigated two main questions:
    a. Does the EAT programme help non-smokers to remain abstinent?
    b. Does the EAT programme encourage smokers to take steps to stop smoking?

2) To assess whether the programme is equally effective for participants of different gender, social and cultural backgrounds, we investigated the questions:
    a. Is the EAT programme equally effective for both genders?
    b. Is the EAT programme equally effective for different school types?
    c. Is the EAT programme equally effective for different cultural backgrounds?

Methods

Intervention

The programme consists of two 60-minute modules. The first part is 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 consists of an interactive

PowerPoint presentation in which the participants are encouraged to make their own well-informed decisions and receive relevant knowledge on handling confrontations with their peers (social competence approach). The university hospital patient with a smoking-related disease is interviewed about his reasons to start smoking and the influence tobacco consumption had on his life. The participants are encouraged to ask the patient questions. The second part takes place in an interactive classroom setting in which two medical students (usually a male and a female) tutor one class. Both modules focus 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). The participants also discuss information relevant for their age group, e.g., why non-smokers look usually more attractive, have more money to buy things, or are in better physical shape. The programme focuses on not scaring but educating its participants in an interactive manner. EAT uses a combined social influences and social competences approach, which was described as the most effective approach in the recently published Cochrane Analysis [13].

Study design and setting

Design

The survey is designed as a quasi-experimental prospective evaluative study with two measurements (baseline and 6 months post-intervention). The planned study period is October 2013 until July of 2014. Participants in two study groups

(intervention and control groups) will be questioned up to 2 weeks in advance of the intervention (t1) and 6 months thereafter (t2) (see Figure 1).

Randomization could not be performed due to the tremendous organizational and personal effort required for it. Some classes refused to participate when informed that they would be control groups. To keep confounding factors to a minimum, a parallel class in a given grade was selected as the control group. All participating schools were asked in advance to split their grades into two class-groups with the same performance levels. Schools that did not agree to the splitting procedure were excluded. A parallel class is defined as a control class in the same grade as the intervention class, with the same performance level as the intervention class, and attending the same school as the intervention class. All intervention classes had parallel classes. We chose to do the follow-up at six months so that the control group could receive the intervention in the same school year (after data collection was completed). This made it easier for us to convince schools to participate.

Data collection

A written survey questionnaire is used for the collection of the data. The questionnaire was developed to collect data at both time points (t1-t2). In addition to the socio-demographic data (age, gender, school type), it will capture the smoking status of the school students concerning water pipe and cigarette consumption. To maximize the external validity of the intervention, the questionnaires will be placed in envelopes which are instantly being sealed by the responsible class teachers immediately after completion.

Data management and analysis

The envelopes will be opened and data analysis performed under the supervision of Prof. Dr. Groneberg at the Goethe University of Frankfurt. The class teachers will individually supervise their classes during the completion of the questionnaire.

The questionnaire contains numerous items which have already been included in similar investigations. The questions about the smoking status and the frequency of smoking refer to the evaluation of the school-based smoking prevention programmes in Heidelberg entitled “Ohne Kippe” (No Butts) [20] and in Berlin entitled “Students in the hospital” [14] as well as to the results of the KiGGs child and adolescent surveys published by Lampert and Thamm [21].

To test the questionnaire in accordance to the GEP guidelines [22], we distributed 88 copies to pupils with the lowest education level in May 2013. 85 of the completed questionnaires were deemed as a useful way for evaluation, but seven had not been filled out completely. Therefore, we added a note to turn the page at the bottom of each page to fix this problem.

Participants and sample size

Eligibility criteria

Students aged 10 to 15 attending grades six to eight of a secondary general, intermediate, grammar, or comprehensive school are eligible. Older or younger students or students from other school types are not. Schools in Gießen and the surrounding area already participate in the programme each year. They know that participation is voluntary and can be ended at any time without giving a reason. The

geographical area concerned (Gießen and surrounding villages) was informed about the study via the Hessian Ministry of Education and Cultural Affairs.

Legal approval

In accordance with Good Epidemiologic Practice (GEP) guidelines [22], the study protocol was submitted for approval by the responsible ethics committee, which decided that the study does not need ethical approval (ethics committee of Goethe University, Frankfurt-Main, Germany). All legal and data protection issues were discussed with the responsible authority, the Ministry of Education and Cultural Affairs in Germany, which approved the proposed data collection within the participating schools. In addition, each school individually discussed and approved the study at a school conference. It was explained to each student that participation is voluntarily, and informed written consent was obtained from the parents of the study participants.

Sample Size Calculation

As there is no other evaluated school-based programme delivered by medical students, our study has an explorative character. Still, we decided to calculate the sample size (using the programme BiAS for Windows) on the basis of a recently published study which evaluated the “Non-smoking is Cool” school-based physician delivered programme in Hamburg [17]. To calculate the sample based on effect size requirements, we used the difference in the number of persons who started smoking within nine months between the intervention and control group at grammar schools investigated in the reference study (6.4% in the intervention group vs. 12% in the control group yields a difference of 5.6%) [15]. We decided to use the method of Sack et al. for our calculations because ”Students in the Hospital” mainly included school types with a lower educational level. We used the rates for

grammar school students, who will be the largest group of participants in our study. Thus, we calculated that the required sample size is 435 pupils per group (870 total), plus the loss to follow-up group at a test power of 80% (alpha = 0.05). We took into account the loss to follow-up effect of “Students in the Hospital” (17,8%), which increased our group size to n1 = 514 and n2 = 514 (total: 1028) [14].

(Figure1.tiff (stored seperately))

Gender specific aspects

Our recent study using the physician-based approach for school-based tobacco prevention [14] showed that girls benefit from physician-delivered programmes more than boys (OR 2.56, CI 1.06–6.19). We aim to assess whether this effect is also observed using the EAT medical student-based approach. If so, the programme will be modified for gender mainstreaming since both sexes need to be addressed equally.

Cultural aspects

We hypothesize that there will be a small but significant relation between water pipe smoking and cultural background since water pipe use is traditional in the Middle East region [23]. Therefore, we plan to collect data on the cultural background of the students. Comprehensive information about water pipe smoking is an integral component of the EAT programme. Within the proposed optimization process, the EAT curriculum can be tailored to the different school populations (e.g., schools with or without a high percentage of pupils with a migration background) as needed.

Social aspects

According to a survey conducted by the Federal Centre for Health Education [5], the prevalence of cigarette smoking in 10- to 15-year-olds in Germany was significantly higher in schools with lower education levels in 2012 (16.7% vs. 6.9%). Consequently, we plan to specifically address schools with lower education levels and to compare the effects of the intervention on different school types.

Outcomes

The primary endpoint is the percentage difference between smokers and non-smokers in the two study arms at baseline and 6 months after the intervention (lifetime prevalence). The percentage of former smokers and new smokers in the two groups and the measures of smoking behaviour (the number of cigarettes and water pipes smoked on a daily, weekly or monthly basis) will be studied as secondary outcome measures.

Statistical analysis

In order to examine baseline differences of pupils' characteristics in our quasi-experimental design we will use χ^2-tests for the categorical variables and t-tests for continuous variables. There must be no significant differences between the two study groups at baseline (t1). The effects of predictors on the smoking behaviour after six months (t2) will be calculated by logistic regression analysis, a state-of-the-art technique for the evaluation of the effectiveness of prevention programmes [20, 24, 25] in longitudinal studies. The significance level is 5% for t-tests (double-sided) and 95% for confidence intervals (double-sided). The statistical analysis will be performed using the newest version of SPSS Statistics for Mac by IBM.

Discussion

Strengths and limitations

No evaluation of a medical student-delivered school-based tobacco prevention programme is available to date. It is imperative to sensitize prospective physicians to tobacco prevention [12]. An additional aim of this study is to evaluate whether a medical student-delivered smoking prevention program has preventive effects on the smoking behaviour of secondary school pupils in Germany. The data from this study will provide a sound basis for optimizing the Education Against Tobacco curriculum to make it optimally effective for different target groups. A promising factor of the EAT programme is that it uses a combined social influence and social competence approach, which was been shown to be effective in the recently published Cochrane Analysis [13].

Our study has a quasi-experimental design. The main problem of this kind of study is selection bias due to the lack of randomization. To minimize this problem, we will match the intervention classes with parallel control classes (same grade and school), which corresponds to the matching procedure in field experiments.

As the intervention and control groups attend the same schools, the pupils could exchange what they learn about smoking in the intervention during school breaks. Therefore cluster effects cannot be excluded entirely.

Also, as our research is not multi-national, it might not be useful for persons of all ethnic and cultural backgrounds.

Because our study relies on self-reports obtained from adolescents via a questionnaire for data collection, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, e.g. due to social desirability bias.

This bias can only be excluded by using expensive methods like testing for cotinine (a metabolite of nicotine) in the saliva, blood or urine of the students. Other alternatives described by Ketala et al. (2004) include the measurement of thiocyanate in saliva or carbon monoxide in exhaled air [26]. This group reported 95% agreement between the results of these biochemical tests and the results of questionnaires. Conversely, Connor Gorber et al. (2009) found high differences between biochemically assessed and self-reported smoking status in pregnant women and patients with tobacco-related diseases [27]. In our study, there might be social desirability bias in both study groups, which might make the intervention look less effective than it actually is:

The first measurement at baseline occurs while the intervention group is anticipating the intervention. Therefore, more intervention group students might feel compelled to behave in a socially desirable way and falsely declare that they are non-smokers. In contrast, the control group students know that they will not see the medical students again anytime soon, so they might be inclined to answer more honestly to the items on the questionnaire. At the second measurement time point, the situation is reversed: Because the intervention group students know that the medical students will not come back, they might feel less social desirability pressure and be more likely to admit that they are smokers. In contrast, the control group students will be awaiting the next intervention in the coming weeks, so they might reply to the questionnaires in a more socially desired way (declaring that they are non-smokers even if they smoke).

Consequently, the study could be compromised by social desirability bias at both time points, which could make the intervention look less effective.

In order to measure the long-term effects of school-based programmes, follow-up data is usually collected six months and one year after an intervention. However, we will only be able to collect data six months post-intervention because the schools insisted on us providing an intervention for the control group in the same school year. Thus, we will not be able to determine which effects the intervention might have at one year follow-up.

Conclusion

We expect that our research will find general acceptance because the investigated programme provides many medical students and even more medical interns (e.g., in the elective period known) a great opportunity to deliver prevention programmes not only in inpatient secondary prevention, but also and in particular in primary prevention in schools and communities. Health systems worldwide could benefit from the development of such novel and low-cost primary smoking prevention programmes.

Authors' contributions

TJB contributed to the design and conduct of the study, drafted the manuscript, and will perform the statistical analysis. WS supports the coordination of the study. SS-B contributed to the design of the study, participated in the writing process, and proofread the manuscript. DAG contributed to the design of the study 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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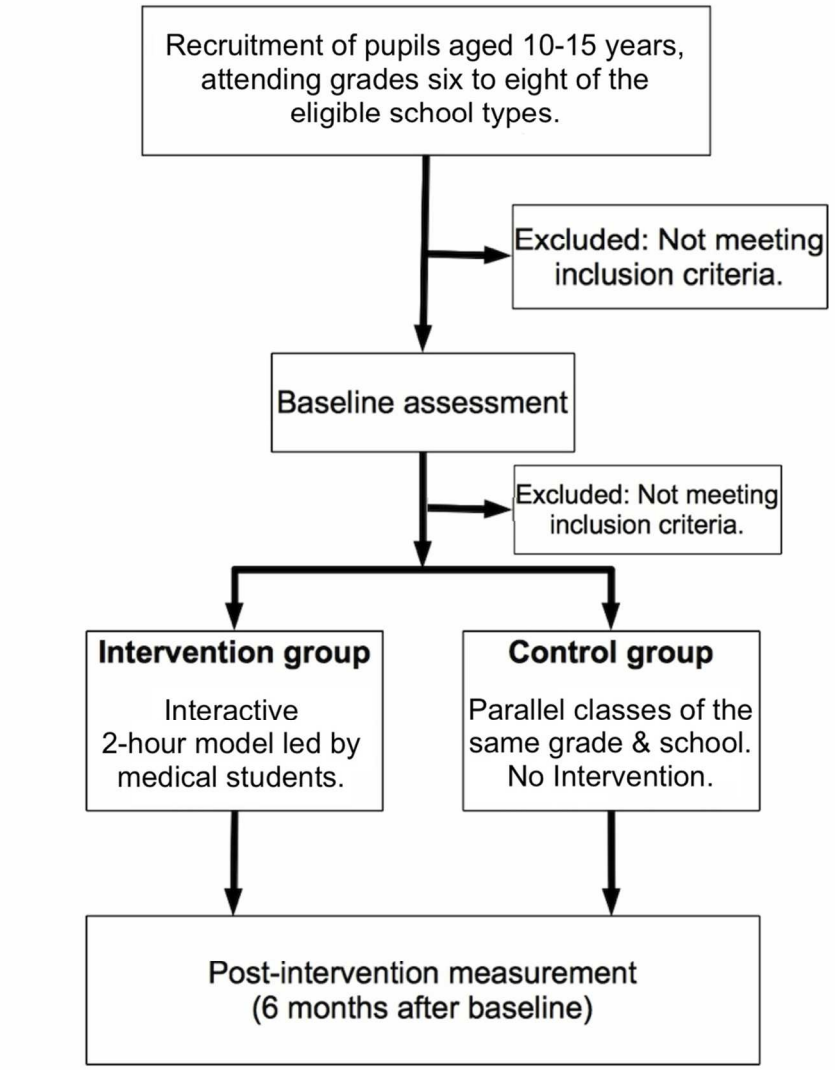

Figure 1
Study design.

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Education ~~Against~~ against Tobacco (EA~~A~~T) - A quasi-experimental prospective e~~E~~valuation of a ~~school-based~~ program for preventing smoking in secondary schools delivered by medical students: a study protocol

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ABSTRACT

Background: In a survey conducted and published by the Federal Centre for Health Education in Germany in 2012 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) described themselves as regular cigarette smokers. Most smokers have consumed their first cigarettes in early adolescence. We recently reported a significantly positive short-term effect of a school-based smoking prevention program on the smoking behaviour of school children delivered by physicians in Germany. Since physician-based programs are usually very expensive, we aim to evaluate and optimize the widespread low-cost program "Education against Tobacco" which is being delivered by about 400 medical students at 16 universities in Germany.

Methods and analysis: Prospective quasi-experimental study design with two measurements at baseline (t1) and 6 months post-intervention (t2) to investigate an intervention in 10- to 15-year-olds in grades six to eight at German secondary schools. The intervention programme consists of two 60-minute school-based medical-student delivered modules with (module 1) and without the involvement of patients with tobacco-related diseases and control groups (no intervention).

~~*Methods/Design:* We perform a quasi-experimental prospective evaluative study including 2 measures (at baseline and 6 months after intervention) prospective case-control study with quasi-experimental design among 10 to 15-year old children of secondary schools in Germany visiting school grades six to eight. The intervention program consists of two medical-student delivered modules within the schools of about 60 minutes duration each. The first module also involves patients with tobacco related diseases. The control group does not receive any intervention.~~

The study questionnaire measuring smoking status (water pipe and cigarette smoking), smoking-related cognitions, and gender, social and cultural aspects was designed and pre-tested in advance. The primary endpoint is the percentage difference between smokers and non-smokers in the two study arms at baseline and 6 months after the intervention. The percentage of former smokers and new smokers in the two groups and the measures of smoking behaviour will be studied as secondary outcome measures.

Ethics and dissemination: In accordance with Good Epidemiologic Practice (GEP) guidelines, the study protocol was submitted for approval by the responsible ethics committee, which decided that the study does not need ethical approval (Goethe University, Frankfurt-Main, Germany). Findings will be disseminated in peer-reviewed journals, at conferences, within our scientific advisory board and through medical students within the EAT project.

~~To collect the data, we designed and pre-tested a questionnaire measuring the smoking status (water pipe and cigarette smoking), smoking-related cognitions as well as gender, social, and cultural aspects. Data will be collected at baseline and six months post the intervention.~~

~~*Discussion:* This study protocol describes the design of a prospective case-control~~intervention ~~study that will evaluate the effectiveness of a school-based smoking prevention program delivered by medical students. We expect that a significantly lower number of children will start smoking in the intervention group compared to the control group as a direct result of this intervention. We will optimize the curriculum on the basis of the results of this evaluation to make it optimally effective for both genders and different ethnic groups.~~

Strengths and limitations of this study

- No medical student-delivered school-based tobacco prevention programme has been evaluated for its primary preventive effect to date.
- It is imperative to sensitize prospective physicians to tobacco prevention.
- The quasi-experimental design of this study might cause a selection bias due to the lack of randomization.
- Cluster effects cannot be excluded entirely as the control classes are located in the same schools and pupils could exchange what they have learned.
- As our research is not multi-national, it might not be useful for persons of all ethnic and cultural backgrounds.
- Because our study relies on self-reports obtained from adolescents via a questionnaire for data collection, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, e.g. due to social desirability bias.
- Our follow-up data is only collected six months after the intervention due to organisational reasons. Thus, we will not be able to determine which effects the intervention might have at one year follow-up.

~~**Strengths and limitations of this study**~~

~~A consequence of our research is suspected to be the general acceptance that medical students and even more medical interns (PJ-medical students) offer a great opportunity to deliver prevention programs. Therefore, health systems worldwide may largely benefit from the development of a novel and low-cost measure of primary prevention. A main limitation would be the fact that our research is not been done multinationally and therefore might not be representative for every ethnical and cultural background. Futhermore, the case and the control groups were in the same~~

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schools which is a potential confounding variable as the pupils could exchange what they have learned about smoking due to the intervention during the school breaks.

Keywords: smoking prevention, school based prevention, primary prevention, medical students, schools, adolescents

Background

Tobacco consumption is a risk factor for various diseases and leads to the highest number of avoidable deaths worldwide [1]. Despite warning labels and public interventions, smoking causes diseases and death in Germany where it was responsible for almost 107.000 deaths in 2007 [2]. In addition, it generates high financial costs. A A study which modelled amounted the costs for acute hospital care, inpatient rehabilitation care, ambulatory care and prescribed drugs caused by smoking in Germany to be 7.5 billion Euro in 2003 of productivity losses due to smoking in Germany for the year 200[3]5 [3] calculated productivity costs of 9.6 billion Euro which were caused by smoking.

Most smokers started smoking in early adolescence [4]. In a survey conducted and published by the Federal Centre for Health Education (Bundeszentrale für gesundheitliche Aufklärung, BZgA) in Germany in 2012 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) described themselves as regular cigarette smokers [5]. A survey conducted in 2006 quantified nicotine dependency with the help of the Fagerström test [6]. It reported that 50.8% of the 15– to 17-year-old smokers and 41.8% of those in the 18– to 24-year age group were dependent on nicotine. Laucht and Schmid reported a correlation between the number of cigarettes smoked and the starting age in 15-year-old adolescents [7]. It

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was demonstrated that the earlier in life they had smoked their first cigarette, the more likely they were still consuming tobacco, the more cigarettes they were currently consuming and the higher was their degree of dependence.

Furthermore, in the past few years there was an increase in the use of water pipes [8]. According to a survey conducted by the Federal Centre for Health Education in 2011, 8.7% of adolescents and 11.2% of the participating young adults had smoked water pipe at least once in the 30 days leading up to the survey [8]. Male respondents have smoked water pipe more frequently than women [8]. According to Maziak, water pipes lead the way to cigarette smoking and have similarly deleterious effects for human health [9].

Early primary prevention of smoking is thus of crucial importance and therefore should be promoted, evaluated and optimized.

There are already scientifically evaluated prevention programs in Germany available like the smokefree class competition (SFC) which has shown a significant primary preventive long-term effect and cost-effectiveness [10, 11]. However, the SFC competition focusses on cigarette consumption exclusively and does not include waterpipe smoking. In addition, there is no comparable beneficiary effect for the instructors of the SFC program. In contrast, EAT additionally sensitizes prospective physicians for the importance of tobacco prevention. As a recent study from Yale University suggests, tobacco addiction is undertreated by physicians in comparison~~m~~ to other chronic conditions [12]. The authors concluded, that alternate models of engagement may be needed to enhance use of effective treatments for tobacco addiction and to rise the awareness among physicians.

So far, medical student delivered school-based programmes for preventing smoking

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have not been evaluated. Therefore, only little relevant data is available in scientific databases such as Medline or PubMed. The most relevant publication on the topic is the Cochrane Database Analysis on school-based programs for preventing smoking [13]. The authors analyzed the data from 134 studies, in 25 different countries, which included a total of 428.293 young people aged 5-18. Of these, 49 studies reported smoking behavior in those adolescents who had never previously smoked. No overall effect of intervention curricula vs. control was found from the pooled results at follow-up at one year or less (odds ratio (OR) 0.94, 95% confidence interval (CI) 0.85 to 1.05)[13]. The most relevant main result for our research is that combined social competence and social influence curricula showed a statistically significant effect for preventing the onset of smoking [13]. The authors concluded that further research is required to design and test programs that will be equally effective for both genders, different cultural backgrounds and ethnic groups. Interventions delivered by adult educators were shown to be more effective in the longer term than peer-education programs. In this respect, medical students belong to the group of adult educators. According to the Cochrane Analysis, cost-effectiveness plays an important role for practical implementation. As EAT is delivered by volunteering medical students, it is less expensive but more available than physician delivered programs.

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However, there are already programs for secondary schools available which involve physicians as health educators. In fact, Stamm-Balderjahn et al. recently published data on a school-based physician delivered program in Germany. Within the evaluation of the physician-based program ”Students in the Hospital” in Berlin, significant positive results were present for a multimodal approach [14].

An anonymous survey by questionnaire from September 2007 to July 2008 was conducted, with a quasi-experimental control-group design, two weeks before (t1)

and six months after (t2) the intervention in a group of 760 participating school students in Berlin.

The results indicated that 40.8% of the participants were smokers at baseline, among whom 79% stated that they also smoked water pipes. As major primary prevention outcome of the study, it was found that significantly fewer students in the intervention group than in the control group began smoking in the six months after the intervention ($p<0.001$). In addition, the chance of remaining a non-smoker was four times as high in the intervention group (OR, 4.14; CI, 1.66–10.36). Concerning gender aspects, girls appeared to benefit more from the intervention than boys (OR 2.56, CI 1.06–6.19)(1). 16.1% of smokers in the intervention group and 17.6% in the control group stopped smoking ($p>0.05$). Conclusively, a clear primary preventive effect of the program was demonstrated.

Another evaluated physician-delivered program is the „non-smoking is cool“ (=NiC) program based in Hamburg (Germany) adressing grades 5 to 6 of all secondary school types (total sample size: 1359 students) [15]. The program states to use a social influence and fear based curriculum. Fear based appeals have multiply been shown to be ineffective on a long-term basis in the field of primary tobacco prevention [16]. However, the program has shown to be effective in grammar schools where it reduced the onset of smoking by 50% in comparism to the control group after three months and nine months of follow up with a low effect size [17]. Nevertheless, in schools with a lower educational level (general, intermediate, or comprehensive school) it failed to show a significant primary preventive effect [17].

Since physician-based programmes are usually very expensive and there is a lack of available physicians, it is indicated to evaluate a less expensive and widespread program which sensitizes prospective physicians for tobacco consumption.

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School-based smoking prevention program delivered by medical students

The Education against Tobacco program is not associated with “Students in the Hospital”.

[12, 18]

~~**School-based smoking prevention program**~~

The registered association „Education ~~against~~ against Tobacco“ (hereinafter referred to as "EAAT") has been founded and developed since August 2011 by medical student Titus Brinker of the University of Gießen in cooperation with professors from the Universities of Gießen, Frankfurt and Marburg as well as fellow students from the Texas A&M University. The program has been developed taking into account the Cochrane ~~Database Systematic Review on school-based programmes for preventing smoking (2006~~Analysis [19]~~)(13)~~ in regard of its conclusion to focus on the development of low cost prevention programs and its implication for research to combine social influences approaches with generic social competence approaches. Both of these key points have been taken into account when developing the cEAT curriculum. ~~.~~ At the time of development there was already research available which encouraged EAAT to use medical students as Sussman et al [20] concluded that health educator-led drug prevention programs are more effective than self-instructed programs.

Since physician-based programs have proven to be successful [14] but usually are very expensive, we aim to evaluate and optimize the widespread low-cost program “~~education~~ Education ~~against~~ against ~~tobacco~~Tobacco“ which is being delivered by about 400 medical students at 16 universities in Germany and ~~,~~ only costs 25 Euro

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per participating class. The city of Gießen provides an ~~excellent~~ useful platform to evaluate this effect as it homes the largest EAA~~A~~T group with the highest experience level and the most participating EAA~~A~~T schools.

Objectives

1) To assess the efficacy of this program, we set out to answer two main questions:
   a. Does the EAT program help nonsmokers to remain abstinent?
   b. Does the EAT program encourage smokers to take steps to give up?

2) To assess if the program is equally effective for participants with different gender, social and cultural backgrounds. The questions are:
   a. Is the EAT program equally effective for both genders?
   b. Is the EAT program equally effective for different school types?
   c. Is the EAT program equally effective for different cultural backgrounds?

~~In the past years, prevention science has emerged as a research discipline built on the integration of life course development research, community epidemiology, and preventive intervention trials. Our objective is to integrate these aspects in order to promote prevention in the area of tobacco addiction with a focus on low cost widespread programs.~~

~~We plan to evaluate the effect on the smoking behavior of the curriculum being delivered by medical students in order to reach a sound basis for a future, nation-wide program. In this connection, we consider gender, social, and cultural aspects of the intervention in order to optimize the curriculum which includes the design of an evidence-based and easy to implement train the trainer EAT program as a consequence of this study by engulfing recent research knowledge on smoking related diseases. By doing this, we plan to improve the education of the health~~

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~~educators (participating medical students) by the use of additional expert knowledge on the topic. This train the trainer program also sensitizes the medical students – regardless of their future medical specialization – towards the needs of tobacco prevention and thus increases the knowledge on prevention among the future physicians.~~

~~Consequently, it is our strategy to perpetuate the program on a national level by developing a system for the integration of EAT into the structure of medical faculties and large teaching hospitals. In this respect, we will customize the project for an integration of EAT into elective courses (Wahlfächer) or cross sectional areas (Querschnittsbereiche) such as prevention (QB10) or environmental medicine (QB6) at the medical schools of the 16 EAT partner universities.~~

Methods

Intervention

The program consists of two parts of 60 minutes duration each. The first part is presented by at least two medical students (up to six) and a patient with a tobacco related disease in front of all pupils at the same time inside a large room within the school. It consists of an interactive powerpoint presentation in which the participants are reinforced to take exclusively their own well-informed decisions while providing them with relevant knowledge for confrontations with their peers (social competence approach). In addition, a patient from the university hospital with a smoking related disease is being interviewed about his reasons to start smoking and the influence tobacco consumption had on his life. The participants are encouraged to ask their own questions to the patient. The second part takes place in an interactive class

room setting with two medical students tutoring one class (usually a male and a female). Both parts educate the adolescents about the strategies of the tobacco industry to influence their decision in an unobjectice manner (social influence), about peer pressure (social influence), decision making and about skills how they can deal with challenges in their life in a healthy way (social competence). In addition, the participants discuss relevant information for their age group e.g. why nonsmokers look usually more attractive, have more money to buy things or are in better shape for physical education. The program focusses on not scaring but educating its participants in an interactive manner. Consequently, the EAT program uses a combined social influences and social competences curriculum which has been shown to be the most effective approach in the recently published Cochrane Analysis [13]. ~~[13]~~

Study design and setting

Design

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The survey will be designed as a quasi-experimental prospective evaluative study including 2 measures (at baseline and 6 months after intervention)~~prospective case-control study with quasi-experimental design~~. The period of time of the survey is planned to be from October 2013 until July of 2014. Participants in two study groups (intervention by medical students and control) will be questioned up to 2 weeks in advance of the intervention (t1) and 6 months thereafter (t2) (see Figure 1).

We could not afford randomization as it includes a huge organizational and personal effort we were not capable to perform. In addition, some classes would not agree to participate within the study when they would be predetermined as control groups

which became clear in advance of the investigation. To keep confounding factors to a minimum, the parallel class of intervention classes in a given grade is selected for the control group. All participating schools were asked in advance to split their grades into two class-groups with the same performance level on their own. Schools who would not agree with the splitting were excluded. Parallel classes are defined as control classes which are in the same grade as the intervention class, have the same performance level as the intervention class and visit the same school as the intervention class. Consequently, all classes have parallel classes. In addition, we chose to do the follow-up after six months so the control group could receive the intervention in the same school year (after data collection is complete) which made it easier for us to cooperate with the schools.

Data collection

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For the collection of the data we will use a written survey in the form of a questionnaire. This questionnaire is developed to collect data to each of the defined time points (t1-t2). In addition to the socio-demographic data (age, gender, school type), we will obtain the smoking status of the school students concerning water pipe and cigarettes. The teachers sign a brief declaration where they state to be fully responsible for the sealing process directly after the questionnaires have been filled out by the pupils.

To maximize the external validity of the intervention, the questionnaires will be put into envelopes which are instantly being sealed by the responsible class teachers after completion.

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~~after completion. The envelopes will be opened and the data evaluation will be performed under the supervision of Prof. Dr. Groneberg at the Goethe University Frankfurt. The class teachers individually supervise their classes for the completion of the questionnaire.~~

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The envelopes will be opened and the data evaluation will be performed under the supervision of Prof. Dr. Groneberg at the Goethe University of Frankfurt. The class teachers individually supervise their classes for the completion of the questionnaire.

The questionnaire will contain numerous items which have already been a part of similar investigations. The questions about the smoking status and the frequency of smoking refer to the evaluation of the school-based smoking prevention program from Heidelberg „ohne Kippe“ [18] and the publication of Lampert and Thamm [21] about the results of the child and adolescent surveys (KiGGS).

~~The period of time of the survey is planned to be from October 2013 until July of 2014. Participants in two study groups (intervention by medical students and control) will be questioned up to 2 weeks in advance of the intervention (t1) and 6 months thereafter (t2) (see Figure 1).~~

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To test the questionnaire in accordance to the GEP guidelines [22], we carried out 88 copies to pupils with the lowest education level participating in May 2013. We investigated that 85 of these questionnaires were filled out in a useful way for evaluation. However, seven pupils did not fill out the questionnaire completely. We added a notification to turn the page at the bottom of each page to fix this problem.

Participants and Sample Size

Eligibility criteria

Students aged 10 to 15 attending grades six to eight of a secondary general, intermediate, grammar, or comprehensive school are eligible. Older or younger students, or students from other school types are persons who do not meet the inclusion criteria. The schools in Gießen and the surrounding cities are already involved in the program and let their classes participate every year. Participation is voluntary and could be ended at any time without giving a reason. The geographical area concerned (Gießen and surrounding villages) was informed via the ministry of cultural affairs in Hessen, Germany.

Legal approval

In accordance to Good Epidemiologic Practice (GEP) guidelines [22], approval of the responsible ethics committee was asked for and the committee decided that the study does not need ethical approval (ethics committee of the Goethe University, Frankfurt am Main, Germany). All legal preparations and data protection issues have been discussed with the responsible ministry of education and cultural affairs in Germany. The ministry gave approval for the stated proceed of data collection within the participating schools. In addition, each school individually discussed and

approved the study in its schools' conference. The participation of each student was declared to be voluntarily and informed written consent was obtained from the parents of the study participants.

Sample Size Calculation

Even though there is no other evaluated school-based program delivered by medical students and our study therefore has an explorative character, we decided to calculate the sample size (using the program BiAS for Windows) on the basis of a recently published study which evaluated the school-based physician delivered program „non-smoking is cool" (=NiC) from Hamburg in Germany [17]. We calculated the sample on the basis of effect size requirements. To do this we used the difference of the rates of participants who started smoking within the time frame of nine months follow up in the intervention and in the control group for grammar schools from the cited study (6,4% = intervention group; 12% = control group; difference = 5,6%)[17]. We decided to use the Sack et al. publication for our calculations because the „Students in the hospital" publication mainly included school types with a lower educational level. We used the rates for grammar schools as students from these schools are suspected to be the largest group among the participants of our study. Our calculated sample size amounts to 435 pupils per group (870 total) plus the loss to follow-up group at a test power of 80% (alpha = 0,05). We took into account the loss to follow-up effect of the „Students in the Hospital" publication (17,8%) which increased our group size to n1 = 514 and n2 = 514 (total: 1028) [14].

((Figure1.tiff (stored seperately))~~We did not calculate the sample size for the reason of the explorative character of the study. The recruitment sample was calculated on the basis of a recently published study [14] and will amount to 1.002 pupils (n1 = 501 participating in the medical students delivered intervention n2 = 501 pupils in the control group) at least at a test power of 80% (alpha = 0,05). In consideration of the~~

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~~loss to follow-up effect, it is planned to include at least 1.200 participants (600 per group).~~

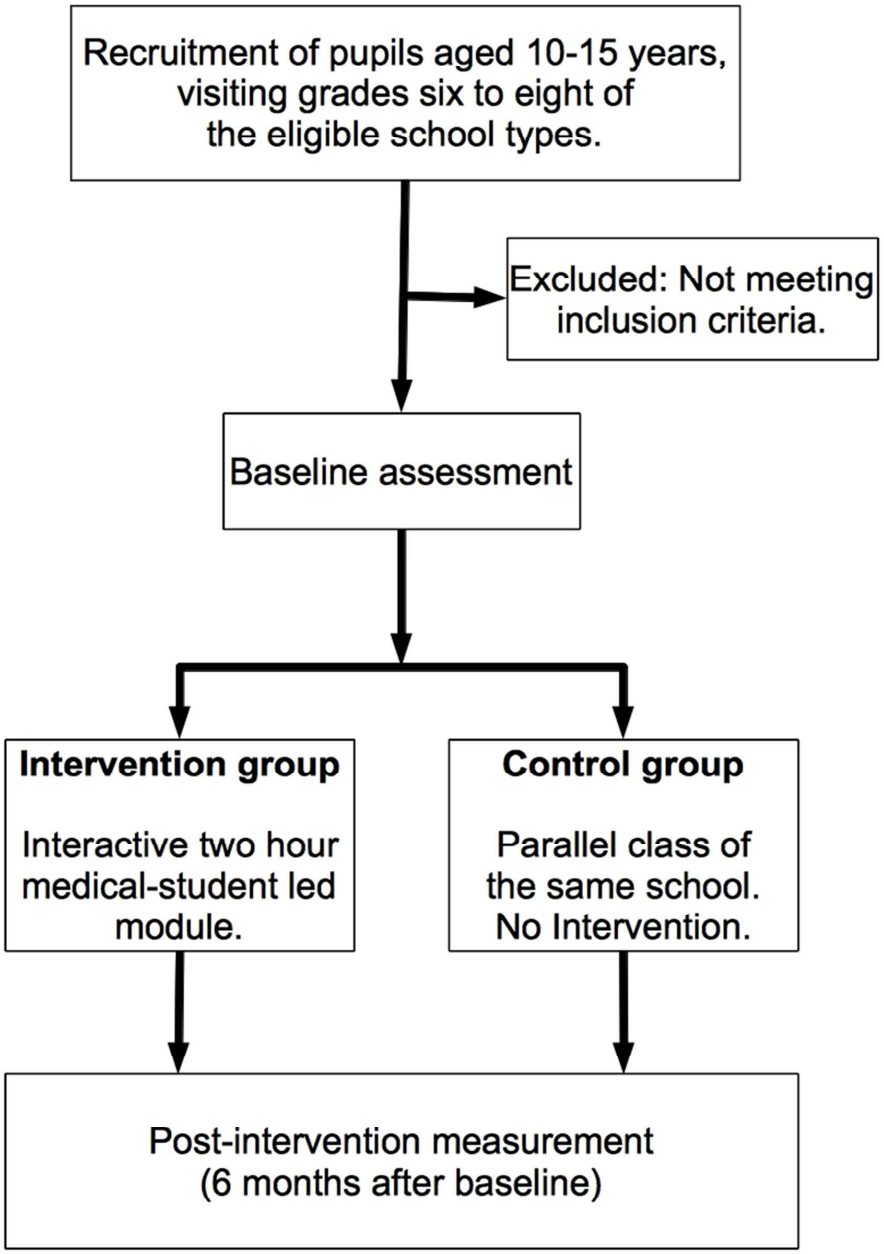

Figure 1
Study design.

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~~**Intervention**~~

~~The intervention consists of two parts of 60 minutes duration each. The first part is delivered in a large room in front of all pupils of the grade including a patient with a tobacco related disease talking about his own experiences with tobacco addiction and an information giving power point presentation. The second session is performed in an interactive classroom setting with two medical students mentoring one class. In advance of the school visit, the medical students receive brief didactic instructions, information on tobacco addiction and FAQs for preparation and a detailed plan of the curriculum. The EAT program uses a combined information giving, social competences and social influences approach.~~

Gender specific aspects

According to our recent study using the physician-based approach for school-based tobacco prevention [14], girls benefit from physician-delivered programs more than boys (OR 2.56, CI 1.06–6.19). We aim to assess if this result is also obtained using the EAAT medical student-based approach to address gender-specific aspects. As a consequence, the program then needs to be modified for gender mainstreaming since both sexes need to be addressed equally.

Cultural aspects

We hypothesize a small but significant relation between water pipe smoking and the cultural background of the pupils since tobacco smoking using a water pipe is traditional in the region of the Middle East [23]. Therefore, we plan to collect data about the cultural background. With regard to this hypothesis, comprehensive information about water pipe smoking is an integrative element of the EAT

curriculum. Within the projected optimization process, the EAT curriculum can also be structured in relation to the different school populations which can be encountered (i.e. schools with a high percentage of pupils of migration background vs. schools without).

Social aspects

According to a survey conducted by the Federal Centre for Health Education [5], the prevalence of cigarette smoking in the age group of 10 to 15 year old pupils was significantly higher in schools with lower education levels in Germany in 2012 (16,7% vs. 6,9%)(16). As a consequence, we plan to specifically address schools with lower education levels and to compare the effects on different school types.

Outcomes

The primary endpoint is the percentage difference between smokers and non-smokers in the two study arms at baseline and 6 months after the intervention (lifetime prevalence). The percentage of former smokers and new smokers in the ~~two~~ two groups and the m~~M~~easures of smoking behavior (the number of cigarettes and water pipes smoked on a daily, weekly or monthly basis) will be studied as secondary outcome measures. ~~We adata concerning~~

Statistical analysis

In order to examine baseline differences of pupils' characteristics in our quasi-experimental design we will use χ^2-tests for the categorical variables and t-tests for continuous variables. No significant differences are aloud between the two study groups at baseline (t1). For the calculation of the effects predictors have on the smoking behavior after six months (t2) we use the logistic regression analysis which is the state-of-the-art technique for the evaluation of the effectiveness of prevention programs ~~In order to detect possible differences at baseline (t1) with regard to the~~

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pupils' characteristics in the intervention group and control group at baseline (t1), we will use χ^2-square-test for binary and categorical variables.

In order to determine relevant effect sizes in consideration of the measurements before and after the intervention, we plan to use the χ^2-square-test for frequency distributions. In addition, we plan to use perform the t-Test/the Wilcoxon-test for mean value differences of paired and unpaired samples. In order to illustrate the attitude towards smoking between the intervention groups and the control group during the time progress of the study we plan to use the univariate variance analysis.

In order to determine relevant effect sizes in consideration of the measurements before and after the intervention (t1/t2), we plan to use the χ^2-square-test for frequency distributions. For the calculation of the predictors of the smoking behavior we use the logistic regression analysis which is the state-of-the-art technique for the evaluation of the effectiveness of prevention programs [18, 24, 25] in longitudinal studies.

Our significance level for t-tests is 5% (double-sided) and for confidence intervals 95% (double-sided). The software for our analysis is planned to be the newest version of SPSS Statistics for Mac by IBM.

The test for significance is planned on the 5% level (double-sided), confidence intervals for 95% (double-sided). The software for our analysis is planned to be the newest version of SPSS Statistics for Mac by IBM.

Discussion

Strengths and limitations

There has never been an evaluation of a medical student-delivered school-based tobacco prevention program. However, sensitizing prospective physicians for tobacco prevention is most necessary [12]. The perspective of this study is to suggest

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whether medical student delivered prevention programs in addition have preventive effects on the smoking behaviour of secondary school pupils in Germany. The data of this study gives us a sound basis for optimizing the EAT curriculum to be optimally effective for different target groups. A promising factor of the EAT program is that it uses a combined social influence and social competence curriculum which has been shown to be effective in the recently published Cochrane Analysis [13].

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Our study has a quasi-experimental design. The main problem of these kind of studies is the selection bias for the reason of the missing randomisation of our target group. To minimize this bias, we will match the intervention classes with the control classes in the same schools which equals the matching procedure in field experiments.

However, as the intervention and the control groups will be in the same schools the pupils could exchange what they learn about smoking due to the intervention during the school breaks. Therefore cluster effects will not be excluded entirely.

Another limitation would be the fact that our research is not being done multinationally and therefore might not be representative for every ethnical and cultural background.

Furthermore, our data collection relies on the self-reports of adolescents using our questionnaire. Consequently, there is a risk that the actual prevalence of smoking is different, e.g. due to socially desirable behaviour. This bias could only be excluded from our survey by using expensive methods like testing for cotinine (a metabolite of nicotine) in the human saliva, blood or urin. Another possible method which has been previously used by Ketala et al (2004) would be the measurement of thiocyanate in the saliva or carbon monoxide concentration in the exhaled air [26]. Ketala et al

reported an accordance of 95% comparing the results from these biochemical methods and the results from the questionnaires.

However, Connor Gorber et al (2009) found high abbreviations between biochemically assessed and self-reported smoking status for pregnant women or for patients with tobacco related diseases [27].

In our study, there might be a bias for socially desired behaviour in both study groups which might make the intervention look less effective than it actually is:

At the first measurepoint the intervention group is awaiting the intervention. Therefore, there might be more pupils who behave in a social desirable way and declare themselves as non-smokers. In contrast, the control group knows that they will not be visited by medical students anytime soon and they might reply more honestly to the items in the questionnaire. At the second measurepoint we have the opposite situation: Our intervention group knows that the medical students will not come back and might now answer in a less socially desired way and declare themselves more likely as smokers. In contrast, the control group is now awaiting the intervention in the upcoming weeks as data collection is complete and might reply to the questionnaires in a more socially desired way (declaring themselves as non-smokers, even if they are not).

Consequently, the effects of the study might be compromised at both time points in a way, which would make the intervention look less effective.

In order to measure the long-term effects of school-based programs to prevent smoking follow-up data is usually being collected after six months and after one year. However, we were only capable of collecting data after six months as the schools

insisted on providing an intervention for the control group in the same school year. Thus, it remains unclear which effects the intervention would show after one year follow-up.

intervention. Therefore cluster effects cannot be excluded entirely.So far, medical student delivered school-based programmes for preventing smoking have not been evaluated. Therefore, only little relevant data is available in scientific databases such as Medline or PubMed. The most relevant publication on the topic is the Cochrane Database Analysis on school-based programs for preventing smoking [13]. The authors analyzed the data from 134 studies, in 25 different countries, which included a total of 428.293 young people aged 5-18. Of these, 49 studies reported smoking behavior in those adolescents who had never previously smoked. The authors concluded that further research is required to design and test programs that will be equally effective for both genders, different cultural backgrounds and ethnic groups. Interventions delivered by adult educators were shown to be more effective in the longer term than peer education programs. In this respect, medical students belong to the group of adult educators. According to the Cochrane Analysis, cost-effectiveness plays an important role for practical implementation. As EAT is delivered by volunteering medical students, it is less expensive but more available than physician delivered programs. [26, 27]

The Cochrane Database Analysis did not include recently published data on school-based health educator delivered programs in Germany. Within the evaluation of the physician-based program "Students in the Hospital" in Berlin, significant positive results were present for an information-based curriculum [14].

An anonymous survey by questionnaire from September 2007 to July 2008 was

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~~conducted, with a quasi-experimental control-group design, two weeks before (t1) and six months after (t2) the intervention in a group of 760 participating school students in Berlin.~~

~~The results indicated that 40.8% of the participants were smokers, among whom 79% stated that they also smoked water pipes. As major primary prevention outcome of the study, it was found that significantly fewer students in the intervention group than in the control group began smoking in the six months after the intervention (p<0.001). In addition, the chance of remaining a non-smoker was four times as high in the intervention group (OR, 4.14; CI, 1.66–10.36). Concerning gender aspects, girls appeared to benefit more from the intervention than boys (OR 2.56, CI 1.06–6.19)(1). 16.1% of smokers in the intervention group and 17.6% in the control group stopped smoking (p>0.05). Conclusively, a clear primary preventive effect of the program was demonstrated.~~

~~Since physician-based programmes are usually very expensive, it is indicated to evaluate a less expensive and widespread program.~~

Conclusion

A consequence of our research is suspected to be the general acceptance that medical students and even more medical interns (PJ-medical students) offer a great opportunity to deliver primary prevention programs. This does not only refer to inpatient secondary prevention but especially refers to primary prevention within the community/school. Therefore, ~~the German~~ health system<u>s worldwide</u> may largely benefit from the development of a novel and low-cost measure of primary prevention.

Authors' contributions:

TJB participated in the design of the study, carries out the study, drafted the manuscript and is supposed to perform the statistical analysis. WS supports the coordination of the study. SS-B participated in the design of the study, participated in the writing process and corrected the manuscript. DAG participated in the design of the study and corrected the manuscript. All authors read and approved the final manuscript. This study is part of a thesis project (TJB).

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Competing interests:

The authors declare that they have no competing interests.

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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 programme for preventing smoking in secondary schools delivered by medical students: a study protocol

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Education Against Tobacco (EAT) - A quasi-experimental prospective evaluation of a programme for preventing smoking in secondary schools delivered by medical students: a study protocol

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ABSTRACT

Introduction: A survey conducted by the German Federal Centre for Health Education in 2012 showed that 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) in Germany are regular cigarette smokers. Most consumed their first cigarette in early adolescence. We recently reported a significantly positive short-term effect of a physician-delivered school-based smoking prevention programme on the smoking behaviour of school children in Germany. However, physician-based programmes are usually very expensive. Therefore, we will evaluate and optimize Education against Tobacco (EAT), a widespread, low-cost programme delivered by about 400 medical students from 16 universities in Germany.

Methods and analysis: Prospective quasi-experimental study design with two measurements at baseline (t1) and 6 months post-intervention (t2) to investigate an intervention in 10- to 15-year-olds in grades six to eight at German secondary schools. The intervention programme consists of two 60-minute school-based medical-student delivered modules with (module 1) and without the involvement of patients with tobacco-related diseases and control groups (no intervention). The study questionnaire measuring smoking status (water pipe and cigarette smoking), smoking-related cognitions, and gender, social and cultural aspects was designed and pre-tested in advance. The primary endpoint is the percentage difference between smokers and non-smokers in the two study arms at baseline and 6 months after the intervention. The percentage of former smokers and new smokers in the two groups and the measures of smoking behaviour will be studied as secondary outcome measures.

Ethics and dissemination: In accordance with Good Epidemiologic Practice (GEP) guidelines, the study protocol was submitted for approval by the responsible ethics committee, which decided that the study does not need ethical approval (Goethe University, Frankfurt-Main, Germany). Findings will be disseminated in peer-reviewed journals, at conferences, within our scientific advisory board and through medical students within the EAT project.

Strengths and limitations of this study

- No medical student-delivered school-based tobacco prevention programme has been evaluated for its primary preventive effect to date.
- It is imperative to sensitize prospective physicians to tobacco prevention.
- The quasi-experimental design of this study might cause a selection bias due to the lack of randomization.
- Cluster effects cannot be excluded entirely as the control classes are located in the same schools and pupils could exchange what they have learned.
- As our research is not multi-national, it might not be useful for persons of all ethnic and cultural backgrounds.
- Because our study relies on self-reports obtained from adolescents via a questionnaire for data collection, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, e.g. due to social desirability bias.
- Our follow-up data is only collected six months after the intervention due to organisational reasons. Thus, we will not be able to determine which effects the intervention might have at one year follow-up.

Background

Tobacco consumption is a risk factor for various diseases and leads to the highest number of avoidable deaths worldwide [1]. Despite warning labels and public interventions, smoking was responsible for almost 107,000 deaths in Germany alone in 2007 [2]. There are high costs associated with smoking. One study estimated the smoking-related costs for acute hospital care, inpatient rehabilitation care, ambulatory care and prescription drugs in Germany to be EUR 7.5 billion in 2003 [3].

Most smokers started smoking in early adolescence [4]. In a survey conducted by the German Federal Centre for Health Education (BZgA) in 2012, 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) in Germany described themselves as regular cigarette smokers [5]. A 2006 survey that quantified nicotine dependence in Germany using the Fagerström test [6] reported that 50.8% of the 15- to 17-year-old smokers and 41.8% of the 18- to 24-year-old smokers were dependent on nicotine. Laucht and Schmid [7] reported a correlation between the number of cigarettes smoked by 15-year-olds and the starting age of smoking; moreover, those adolescents who had started smoking earlier in life were more likely to be still consuming tobacco and to consume more cigarettes and have a higher degree of dependence than their peers.

Furthermore, the use of water pipes has increased in the past few years [8]. According to a 2011 survey by the Federal Centre for Health Education, 8.7% of adolescents and 11.2% of young adults surveyed had smoked water pipe at least once in the 30 days leading up to the survey [8]. Male respondents smoked water pipe more frequently than women [8]. According to Maziak, water pipes lead the way to cigarette smoking and have similarly deleterious effects on human health [9]. Early primary prevention of smoking is thus of crucial importance and should be promoted,

evaluated and optimized.

Some scientifically evaluated smoking prevention programmes already exist in Germany, like the Smoke-Free Class (SFC) competition which has been practically implemented in many countries of the European Union [10-12]. However, the only study of the SFC competition which reported a significant effect on the prevention of smoking at the longest follow-up had multiple biases according to the recent Cochrane Database Systematic Review on incentives for preventing smoking in adolescents by Johnston et al. [12]. In addition, Johnston et al. calculated the adjusted relative risk (RR) of the study and no longer detected a statistically significant difference [12]. Finally, the authors concluded that there are no incentive programmes available to date which have shown to prevent smoking initiation among youth [12].

In addition to that, the SFC competition focuses only on cigarettes and not on water pipe smoking. Furthermore, there is no comparable beneficial effect for the instructors of the SFC programme. Education Against Tobacco additionally sensitizes prospective physicians to the importance of tobacco prevention. A recent study from Yale University suggests that tobacco addiction is undertreated by physicians in comparison to other chronic conditions [13]. The authors concluded that alternative models of engagement may be needed to enhance use of effective treatments for tobacco addiction and to raise awareness among physicians.

To our knowledge, medical student delivered school-based programmes for preventing smoking have not been evaluated to date. Little relevant data is available in scientific databases such as Medline or PubMed. The most relevant publication on the topic is the Cochrane Database Analysis on school-based programmes for preventing smoking [14]. The authors analyzed the data from 134 studies in 25

different countries in a total of 428,293 young people aged 5 to 18. Forty-nine of these studies reported smoking behaviour in adolescents who had never previously smoked. No overall effect of intervention curricula vs. control was found based on the pooled results at follow-up at one year or less (odds ratio [OR] 0.94, 95% confidence interval [CI] 0.85 to 1.05) [14]. From our perspective, the most relevant finding of the Cochrane Analysis is that social competence and social influence curricula have a statistically significant effect of preventing the onset of smoking [14]. The authors concluded that further research is required to design and test programmes that will be equally effective for people of different genders, cultural backgrounds and ethnic groups. Interventions delivered by adult educators were shown to be more effective in the longer term than peer-education programmes. Medical students belong to the group of adult educators. According to the Cochrane Analysis, cost-effectiveness plays an important role in practical implementation. As Education against Tobacco is delivered by medical student volunteers, it is less expensive and more available than physician-delivered programmes.

Secondary school programmes which involve physicians as health educators already exist. In fact, Stamm-Balderjahn et al. [15] recently published data on a school-based physician-delivered programme (Students in the Hospital) in Berlin, which achieved significant positive results with a multimodal approach .From September 2007 to July 2008, they conducted an anonymous questionnaire survey with a quasi-experimental control group design two weeks before (t1) and six months after (t2) the intervention in a group of 760 participating school students in Berlin. The results indicated that 40.8% of the participants were smokers at baseline, 79% of whom stated that they also smoked water pipes. Regarding the primary prevention outcome of the study, it was found that significantly fewer students in the intervention group began smoking

within six months of the intervention than in the control group (p<0.001). In addition, the chance of remaining a non-smoker was four times higher in the intervention group (OR, 4.14; CI, 1.66–10.36). Concerning gender, girls appeared to benefit more from the intervention than boys (OR 2.56, CI 1.06–6.19). 16.1% of smokers in the intervention group and 17.6% in the control group stopped smoking (p>0.05). A primary preventive effect of the programme was clearly and conclusively demonstrated.

Non-smoking is Cool (NiC), another physician-delivered programme based in Hamburg, Germany, addresses grades 5 to 6 of all secondary school types (total sample size reported: 1359 students) [16]. The programme uses a social influence- and fear-based curriculum. Multiple studies have shown that fear-based appeals are ineffective for primary tobacco prevention in the long term [17]. NiC proved to be effective in grammar schools, where it reduced the onset of smoking in the intervention group by 50% compared to the control group at three and nine months follow-up, but with a small effect size [18]. Nevertheless, it failed to show a significant primary preventive effect in schools with a lower educational level (general, intermediate, or comprehensive school) [18].

Considering the high cost of physician-based programmes and the lack of available physicians, it is indicated to evaluate a less expensive and widespread programme that sensitizes prospective physicians to tobacco prevention.

Gender specific aspects

Our recent study using the physician-based approach for school-based tobacco prevention [15] showed that girls benefit from physician-delivered programmes more than boys (OR 2.56, CI 1.06–6.19). We aim to assess whether this effect is also

observed using the EAT medical student-based approach. If so, the programme will be modified for gender mainstreaming since both sexes need to be addressed equally.

Cultural aspects

We hypothesize that there will be a small but significant relation between water pipe smoking and cultural background since water pipe use is traditional in the Middle East region [19]. Therefore, we plan to collect data on the cultural background of the students. Comprehensive information about water pipe smoking is an integral component of the EAT programme. Within the proposed optimization process, the EAT curriculum can be tailored to the different school populations (e.g., schools with or without a high percentage of pupils with a migration background) as needed.

Social aspects

According to a survey conducted by the Federal Centre for Health Education [5], the prevalence of cigarette smoking in 10- to 15-year-olds in Germany was significantly higher in schools with lower education levels in 2012 (16.7% vs. 6.9%). Consequently, we plan to specifically address schools with lower education levels and to compare the effects of the intervention on different school types.

School-based smoking prevention programme delivered by medical students

Education Against Tobacco (EAT) is a non-profit, medical student-delivered school-based smoking prevention programme founded in August 2011 by Titus Brinker, a medical student at the University of Gießen, and developed in cooperation with professors from the Universities of Gießen, Frankfurt and Marburg as well as medical students from Texas A&M University. The programme takes the Cochrane Analysis

into account [20]. Its mission is to focus on the development of low-cost prevention programmes and their implications for research, and to combine social influences approaches with generic social competence approaches. Both of these key points were taken into account when developing the curriculum. At the time of development, there was already research available that encouraged the use of medical students in such programmes. For example, Sussman et al. [21] concluded that health educator-led drug prevention programmes are more effective than self-instructed programmes.

Since physician-based programmes have proven to be successful [15] but usually are very expensive, we aimed to evaluate and optimize Education Against Tobacco, a widespread low-cost programme which is being delivered by about 400 medical students at 16 universities in Germany. It costs only about EUR 25 per participating class. The city of Gießen, home of the largest EAT group with the highest level of experience and the most participating EAT schools, is an adequate platform to evaluate the effects of EAT.

Objectives

1) To assess the efficacy of the programme, we investigated two main questions:
    a. Does the EAT programme help non-smokers to remain abstinent?
    b. Does the EAT programme encourage smokers to take steps to stop smoking?

2) To assess whether the programme is equally effective for participants of different gender, social and cultural backgrounds, we investigated the questions:
    a. Is the EAT programme equally effective for both genders?
    b. Is the EAT programme equally effective for different school types?
    c. Is the EAT programme equally effective for different cultural backgrounds?

Methods

Design

The survey is designed as a quasi-experimental prospective evaluative study with two measurements (baseline and 6 months post-intervention). The planned study period is October 2013 until July of 2014. Participants in two study groups (intervention and control groups) will be questioned up to 2 weeks in advance of the intervention (t1) and 6 months thereafter (t2) (see Figure 1).

Randomization could not be performed due to the tremendous organizational and personal effort required for it. Some classes refused to participate when informed that they would be control groups. To keep confounding factors to a minimum, a parallel class in a given grade was selected as the control group. All participating schools were asked in advance to split their grades into two class-groups with the same performance levels. Schools that did not agree to the splitting procedure were excluded. A parallel class is defined as a control class in the same grade as the intervention class, with the same performance level as the intervention class, and attending the same school as the intervention class. All intervention classes had parallel classes. We chose to do the follow-up at six months so that the control group could receive the intervention in the same school year (after data collection was completed). This made it easier for us to convince schools to participate.

Participants

Eligibility criteria

Students aged 10 to 15 attending grades six to eight of a secondary general, intermediate, grammar, or comprehensive school are eligible. Older or younger students or students from other school types are not. Schools in Gießen and the surrounding area already participate in the programme each year. They know that participation is voluntary and can be ended at any time without giving a reason. The geographical area concerned (Gießen and surrounding villages) was informed about the study via the Hessian Ministry of Education and Cultural Affairs.

(Figure1.tiff (stored separately))

Intervention

The programme consists of two 60-minute modules. The first part is 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 consists of an interactive PowerPoint presentation in which the participants are encouraged to make their own well-informed decisions and receive relevant knowledge on handling confrontations with their peers (social competence approach). The university hospital patient with a smoking-related disease is interviewed about his reasons to start smoking and the influence tobacco consumption had on his life. The participants are encouraged to ask the patient questions. The second part takes place in an interactive classroom setting in which two medical students (usually a male and a female) tutor one class. Both modules focus 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). The participants also discuss information relevant for their age group, e.g., why non-smokers look usually

more attractive, have more money to buy things, or are in better physical shape. The programme focuses on not scaring but educating its participants in an interactive manner. EAT uses a combined social influences and social competences approach, which was described as the most effective approach in the recently published Cochrane Analysis [14].

Data collection

A written survey questionnaire is used for the collection of the data. The questionnaire was developed to collect data at both time points (t1-t2). In addition to the socio-demographic data (age, gender, school type), it will capture the smoking status of the school students concerning water pipe and cigarette consumption.

The questionnaire contains numerous items which have already been included in similar investigations. The questions about the smoking status and the frequency of smoking refer to the evaluation of the school-based smoking prevention programmes in Heidelberg entitled “ohne kippe” (no butts) [22] and in Berlin entitled “Students in the hospital” [14] as well as to the results of the KiGGs child and adolescent surveys published by Lampert and Thamm [23].

To test the questionnaire in accordance to the GEP guidelines [24], we distributed 88 copies to pupils with the lowest education level in May 2013. 85 of the completed questionnaires were deemed as a useful way for evaluation, but seven had not been filled out completely. Therefore, we added a note to turn the page at the bottom of each page to fix this problem.

The class teachers will individually supervise their classes during the completion of the questionnaire. To maximize the confidentiality of the intervention, the questionnaires will be placed in envelopes which are instantly being sealed by the

responsible class teachers immediately after completion. The envelopes will be opened and the data entry and analysis will be performed under the supervision of Prof. Dr. Groneberg at the Goethe University of Frankfurt.

Outcomes

The primary outcome is the prevalence of smokers and non-smokers at 6 months after the intervention. The percentage of former smokers and new smokers in the two groups and the measures of smoking behaviour (the number of cigarettes and water pipes smoked on a daily, weekly or monthly basis) will be studied as secondary outcome measures. A smoker is defined as a pupil who claims to smoke at least “once a month” within the survey. Those pupils who claim not to smoke at all are defined as non-smokers. In accordance to their answers within the survey, non-smokers will be divided in “former smokers” and in “non-smokers who have never smoked before”.

Statistical analysis

Sample Size Calculation

As there is no other evaluated school-based programme delivered by medical students, our study has an explorative character. Still, we decided to calculate the sample size (using the programme BiAS for Windows) on the basis of a recently published study which evaluated the “Non-smoking is Cool” school-based physician delivered programme in Hamburg [18]. To calculate the sample based on effect size requirements, we used the difference in the number of persons who started smoking within nine months between the intervention and control group at grammar schools investigated in the reference study (6.4% in the intervention group vs. 12% in the control group yields a difference of 5.6%) [16]. We decided to use the method of Sack et al. for our calculations because ”Students in the

Hospital" mainly included school types with a lower educational level. We used the rates for grammar school students, who will be the largest group of participants in our study. Thus, we calculated that the required sample size is 435 pupils per group (870 total), plus the loss to follow-up group at a test power of 80% (alpha = 0.05). We took into account the loss to follow-up effect of "Students in the Hospital" (17,8%), which increased our group size to n1 = 514 and n2 = 514 (total: 1028) [15].

Analysis

In order to examine baseline differences of pupils' characteristics in our quasi-experimental design we will use χ^2-tests for the categorical variables and t-tests for continuous variables. There must be no significant differences between the two study groups at baseline (t1). The effects of predictors (like gender, culture and social characteristics) on the smoking behaviour after six months (t2) will be calculated by logistic regression analysis, a state-of-the-art technique for the evaluation of the effectiveness of prevention programmes [22, 25, 26] in longitudinal studies. The significance level is 5% for t-tests (double-sided) and 95% for confidence intervals (double-sided). The statistical analysis will be performed using the newest version of SPSS Statistics for Mac by IBM.

Legal approval

In accordance with Good Epidemiologic Practice (GEP) guidelines [24], the study protocol was submitted for approval by the responsible ethics committee, which decided that the study does not need ethical approval (ethics committee of Goethe University, Frankfurt-Main, Germany). All legal and data protection issues were discussed with the responsible authority, the Ministry of Education and Cultural Affairs in Germany, which approved the proposed data collection within the

participating schools. In addition, each school individually discussed and approved the study at a school conference. It was explained to each student that participation is voluntarily, and informed written consent was obtained from the parents of the study participants.

Discussion

No evaluation of a medical student-delivered school-based tobacco prevention programme is available to date. It is imperative to sensitize prospective physicians to tobacco prevention [13]. An additional aim of this study is to evaluate whether a medical student-delivered smoking prevention program has preventive effects on the smoking behaviour of secondary school pupils in Germany. The data from this study will provide a sound basis for optimizing the Education Against Tobacco curriculum to make it optimally effective for different target groups. A promising factor of the EAT programme is that it uses a combined social influence and social competence approach, which was been shown to be effective in the recently published Cochrane Analysis [14].

Our study has a quasi-experimental design. The main problem of this kind of study is selection bias due to the lack of randomization. To minimize this problem, we will match the intervention classes with control classes (same grade and school), which corresponds to the matching procedure in field experiments.

As the intervention and control groups attend the same schools, the pupils could exchange what they learn about smoking in the intervention during school breaks. Therefore cluster effects cannot be excluded entirely.

Also, as our research is not multi-national, it might not be useful for persons of all ethnic and cultural backgrounds.

Because our study relies on self-reports obtained from adolescents via a questionnaire for data collection, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, e.g. due to social desirability bias. This bias can only be excluded by using expensive methods like testing for cotinine (a metabolite of nicotine) in the saliva, blood or urine of the students. Other alternatives described by Ketala et al. (2004) include the measurement of thiocyanate in saliva or carbon monoxide in exhaled air [27]. This group reported 95% agreement between the results of these biochemical tests and the results of questionnaires. Conversely, Connor Gorber et al. (2009) found high differences between biochemically assessed and self-reported smoking status in pregnant women and patients with tobacco-related diseases [28]. In our study, there might be social desirability bias in both study groups, which might make the intervention look less effective than it actually is:

The first measurement at baseline occurs while the intervention group is anticipating the intervention. Therefore, more intervention group students might feel compelled to behave in a socially desirable way and falsely declare that they are non-smokers. In contrast, the control group students know that they will not see the medical students again anytime soon, so they might be inclined to answer more honestly to the items on the questionnaire. At the second measurement time point, the situation is reversed: Because the intervention group students know that the medical students will not come back, they might feel less social desirability pressure and be more likely to admit that they are smokers. In contrast, the control group students will be awaiting the next intervention in the coming weeks, so they might reply to the questionnaires in a more socially desired way (declaring that they are non-smokers even if they smoke).

Consequently, the study could be compromised by social desirability bias at both time points, which could make the intervention look less effective.

In order to measure the long-term effects of school-based programmes, follow-up data is usually collected six months and one year after an intervention. However, we will only be able to collect data six months post-intervention because the schools insisted on us providing an intervention for the control group in the same school year. Thus, we will not be able to determine which effects the intervention might have at one year follow-up.

Conclusion

We expect that our research will find general acceptance because the investigated programme provides many medical students and even more medical interns (e.g., in the elective period known) a great opportunity to deliver prevention programmes not only in inpatient secondary prevention, but also and in particular in primary prevention in schools and communities. Health systems worldwide could benefit from the development of such novel and low-cost primary smoking prevention programmes.

Funding:

Each participating school pays a small fee for the copies of the questionnaire that are being distributed to every participating student. There are no other funding sources available.

Authors' contributions

TJB contributed to the design and conduct of the study, drafted the manuscript, and will perform the statistical analysis. WS supports the coordination of the study. SS-B contributed to the design of the study, participated in the writing process, and proofread the manuscript. DAG contributed to the design of the study 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.

Data Sharing Statement:

No additional data available

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Education Against Tobacco (EAT) - A quasi-experimental prospective evaluation of a programme for preventing smoking in secondary schools delivered by medical students: a study protocol

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ABSTRACT

~~*Background*~~*Introduction:* A survey conducted by the German Federal Centre for Health Education in 2012 showed that 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) in Germany are regular cigarette smokers. Most consumed their first cigarette in early adolescence. We recently reported a significantly positive short-term effect of a physician-delivered school-based smoking prevention programme on the smoking behaviour of school children in Germany. However, physician-based programmes are usually very expensive. Therefore, we will evaluate and optimize Education against Tobacco (EAT), a widespread, low-cost programme delivered by about 400 medical students from 16 universities in Germany.

Methods and analysis: Prospective quasi-experimental study design with two measurements at baseline (t1) and 6 months post-intervention (t2) to investigate an intervention in 10- to 15-year-olds in grades six to eight at German secondary schools. The intervention programme consists of two 60-minute school-based medical-student delivered modules with (module 1) and without the involvement of patients with tobacco-related diseases and control groups (no intervention). The study questionnaire measuring smoking status (water pipe and cigarette smoking), smoking-related cognitions, and gender, social and cultural aspects was designed and pre-tested in advance. The primary endpoint is the percentage difference between smokers and non-smokers in the two study arms at baseline and 6 months after the intervention. The percentage of former smokers and new smokers in the two groups and the measures of smoking behaviour will be studied as secondary outcome measures.

Ethics and dissemination: In accordance with Good Epidemiologic Practice (GEP) guidelines, the study protocol was submitted for approval by the responsible ethics committee, which decided that the study does not need ethical approval (Goethe University, Frankfurt-Main, Germany). Findings will be disseminated in peer-reviewed journals, at conferences, within our scientific advisory board and through medical students within the EAT project.

Strengths and limitations of this study

- No medical student-delivered school-based tobacco prevention programme has been evaluated for its primary preventive effect to date.
- It is imperative to sensitize prospective physicians to tobacco prevention.
- The quasi-experimental design of this study might cause a selection bias due to the lack of randomization.
- Cluster effects cannot be excluded entirely as the control classes are located in the same schools and pupils could exchange what they have learned.
- As our research is not multi-national, it might not be useful for persons of all ethnic and cultural backgrounds.
- Because our study relies on self-reports obtained from adolescents via a questionnaire for data collection, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, e.g. due to social desirability bias.
- Our follow-up data is only collected six months after the intervention due to organisational reasons. Thus, we will not be able to determine which effects the intervention might have at one year follow-up.

Background

Tobacco consumption is a risk factor for various diseases and leads to the highest number of avoidable deaths worldwide [1]. Despite warning labels and public interventions, smoking was responsible for almost 107,000 deaths in Germany alone in 2007 [2]. There are high costs associated with smoking. One study estimated the smoking-related costs for acute hospital care, inpatient rehabilitation care, ambulatory care and prescription drugs in Germany to be EUR 7.5 billion in 2003 [3].

Most smokers started smoking in early adolescence [4]. In a survey conducted by the German Federal Centre for Health Education (BZgA) in 2012, 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12 to 17 years) in Germany described themselves as regular cigarette smokers [5]. A 2006 survey that quantified nicotine dependence in Germany using the Fagerström test [6] reported that 50.8% of the 15- to 17-year-old smokers and 41.8% of the 18- to 24-year-old smokers were dependent on nicotine. Laucht and Schmid [7] reported a correlation between the number of cigarettes smoked by 15-year-olds and the starting age of smoking; moreover, those adolescents who had started smoking earlier in life were more likely to be still consuming tobacco and to consume more cigarettes and have a higher degree of dependence than their peers.

Furthermore, the use of water pipes has increased in the past few years [8]. According to a 2011 survey by the Federal Centre for Health Education, 8.7% of adolescents and 11.2% of young adults surveyed had smoked water pipe at least once in the 30 days leading up to the survey [8]. Male respondents smoked water pipe more frequently than women [8]. According to Maziak, water pipes lead the way to cigarette smoking and have similarly deleterious effects on human health [9]. Early primary prevention of smoking is thus of crucial importance and should be promoted,

evaluated and optimized.

Some scientifically ~~validated~~ evaluated smoking prevention programmes already exist in Germany, like the Smoke-Free Class (SFC) competition~~, which was shown to have a significant primary preventive long-term effect and cost-effectiveness~~ which has been practically implemented in many countries of the European Union [10-12]. However, the only study of the SFC competition which reported a significant effect on the prevention of smoking at the longest follow-up had multiple biases according to the recent Cochrane Database Systematic Review on incentives for preventing smoking in adolescents by Johnston et al. [12]. In addition, Johnston et al. calculated the adjusted relative risk (RR) of the study and no longer detected a statistically significant difference [12]. Finally, the authors concluded that there are no incentive programmes available to date which have shown to prevent smoking initiation among youth [12].

In addition to that, ~~However,~~ the SFC competition focuses only on cigarettes and not on water pipe smoking. Furthermore~~In addition~~, there is no comparable beneficial effect for the instructors of the SFC programme. Education Against Tobacco additionally sensitizes prospective physicians to the importance of tobacco prevention. A recent study from Yale University suggests that tobacco addiction is undertreated by physicians in comparison to other chronic conditions [13]. The authors concluded that alternative models of engagement may be needed to enhance use of effective treatments for tobacco addiction and to raise awareness among physicians.

To our knowledge, medical student delivered school-based programmes for preventing smoking have not been evaluated to date. Little relevant data is available in scientific databases such as Medline or PubMed. The most relevant publication on

the topic is the Cochrane Database Analysis on school-based programmes for preventing smoking [14]. The authors analyzed the data from 134 studies in 25 different countries in a total of 428,293 young people aged 5 to 18. Forty-nine of these studies reported smoking behaviour in adolescents who had never previously smoked. No overall effect of intervention curricula vs. control was found based on the pooled results at follow-up at one year or less (odds ratio [OR] 0.94, 95% confidence interval [CI] 0.85 to 1.05) [14]. From our perspective, the most relevant finding of the Cochrane Analysis is that social competence and social influence curricula have a statistically significant effect of preventing the onset of smoking [14]. The authors concluded that further research is required to design and test programmes that will be equally effective for people of different genders, cultural backgrounds and ethnic groups. Interventions delivered by adult educators were shown to be more effective in the longer term than peer-education programmes. Medical students belong to the group of adult educators. According to the Cochrane Analysis, cost-effectiveness plays an important role in practical implementation. As Education against Tobacco is delivered by medical student volunteers, it is less expensive and more available than physician-delivered programmes.

Secondary school programmes which involve physicians as health educators already exist. In fact, Stamm-Balderjahn et al. [15] recently published data on a school-based physician-delivered programme (Students in the Hospital) in Berlin, which achieved significant positive results with a multimodal approach .From September 2007 to July 2008, they conducted an anonymous questionnaire survey with a quasi-experimental control group design two weeks before (t1) and six months after (t2) the intervention in a group of 760 participating school students in Berlin. The results indicated that 40.8% of the participants were smokers at baseline, 79% of whom stated that they

also smoked water pipes. Regarding the primary prevention outcome of the study, it was found that significantly fewer students in the intervention group began smoking within six months of the intervention than in the control group ($p<0.001$). In addition, the chance of remaining a non-smoker was four times higher in the intervention group (OR, 4.14; CI, 1.66–10.36). Concerning gender, girls appeared to benefit more from the intervention than boys (OR 2.56, CI 1.06–6.19). 16.1% of smokers in the intervention group and 17.6% in the control group stopped smoking ($p>0.05$). A primary preventive effect of the programme was clearly and conclusively demonstrated.

Non-smoking is Cool (NiC), another physician-delivered programme based in Hamburg, Germany, addresses grades 5 to 6 of all secondary school types (total sample size reported: 1359 students) [16]. The programme uses a social influence- and fear-based curriculum. Multiple studies have shown that fear-based appeals are ineffective for primary tobacco prevention in the long term [17]. NiC proved to be effective in grammar schools, where it reduced the onset of smoking in the intervention group by 50% compared to the control group at three and nine months follow-up, but with a small effect size [18]. Nevertheless, it failed to show a significant primary preventive effect in schools with a lower educational level (general, intermediate, or comprehensive school) [18].

Considering the high cost of physician-based programmes and the lack of available physicians, it is indicated to evaluate a less expensive and widespread programme that sensitizes prospective physicians to tobacco prevention.

Gender specific aspects

Our recent study using the physician-based approach for school-based tobacco prevention [15] showed that girls benefit from physician-delivered programmes more than boys (OR 2.56, CI 1.06–6.19). We aim to assess whether this effect is also observed using the EAT medical student-based approach. If so, the programme will be modified for gender mainstreaming since both sexes need to be addressed equally.

Cultural aspects

We hypothesize that there will be a small but significant relation between water pipe smoking and cultural background since water pipe use is traditional in the Middle East region [19]. Therefore, we plan to collect data on the cultural background of the students. Comprehensive information about water pipe smoking is an integral component of the EAT programme. Within the proposed optimization process, the EAT curriculum can be tailored to the different school populations (e.g., schools with or without a high percentage of pupils with a migration background) as needed.

Social aspects

According to a survey conducted by the Federal Centre for Health Education [5], the prevalence of cigarette smoking in 10- to 15-year-olds in Germany was significantly higher in schools with lower education levels in 2012 (16.7% vs. 6.9%). Consequently, we plan to specifically address schools with lower education levels and to compare the effects of the intervention on different school types.

School-based smoking prevention programme delivered by medical students

Education Against Tobacco (EAT) is a non-profit, medical student-delivered school-based smoking prevention programme founded in August 2011 by Titus Brinker, a

medical student at the University of Gießen, and developed in cooperation with professors from the Universities of Gießen, Frankfurt and Marburg as well as medical students from Texas A&M University. The programme takes the Cochrane Analysis into account [20]. Its mission is to focus on the development of low-cost prevention programmes and their implications for research, and to combine social influences approaches with generic social competence approaches. Both of these key points were taken into account when developing the curriculum. At the time of development, there was already research available that encouraged the use of medical students in such programmes. For example, Sussman et al. [21] concluded that health educator-led drug prevention programmes are more effective than self-instructed programmes.

Since physician-based programmes have proven to be successful [15] but usually are very expensive, we aimed to evaluate and optimize Education Against Tobacco, a widespread low-cost programme which is being delivered by about 400 medical students at 16 universities in Germany. It costs only about EUR 25 per participating class. The city of Gießen, home of the largest EAT group with the highest level of experience and the most participating EAT schools, is an adequate platform to evaluate the effects of EAT.

Objectives

1) To assess the efficacy of the programme, we investigated two main questions:
    a. Does the EAT programme help non-smokers to remain abstinent?
    b. Does the EAT programme encourage smokers to take steps to stop smoking?

2) To assess whether the programme is equally effective for participants of different gender, social and cultural backgrounds, we investigated the questions:

a. Is the EAT programme equally effective for both genders?
b. Is the EAT programme equally effective for different school types?
c. Is the EAT programme equally effective for different cultural backgrounds?

Methods

~~Intervention~~

~~The programme consists of two 60-minute modules. The first part is 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 consists of an interactive PowerPoint presentation in which the participants are encouraged to make their own well-informed decisions and receive relevant knowledge on handling confrontations with their peers (social competence approach). The university hospital patient with a smoking-related disease is interviewed about his reasons to start smoking and the influence tobacco consumption had on his life. The participants are encouraged to ask the patient questions. The second part takes place in an interactive classroom setting in which two medical students (usually a male and a female) tutor one class. Both modules focus 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). The participants also discuss information relevant for their age group, e.g., why non-smokers look usually more attractive, have more money to buy things, or are in better physical shape. The programme focuses on not scaring but educating its participants in an interactive manner. EAT uses a combined social influences and social competences approach,~~

~~which was described as the most effective approach in the recently published Cochrane Analysis [14].~~

~~Study design and setting~~

~~Design~~Design

The survey is designed as a quasi-experimental prospective evaluative study with two measurements (baseline and 6 months post-intervention). The planned study period is October 2013 until July of 2014. Participants in two study groups (intervention and control groups) will be questioned up to 2 weeks in advance of the intervention (t1) and 6 months thereafter (t2) (see Figure 1).

Randomization could not be performed due to the tremendous organizational and personal effort required for it. Some classes refused to participate when informed that they would be control groups. To keep confounding factors to a minimum, a parallel class in a given grade was selected as the control group. All participating schools were asked in advance to split their grades into two class-groups with the same performance levels. Schools that did not agree to the splitting procedure were excluded. A parallel class is defined as a control class in the same grade as the intervention class, with the same performance level as the intervention class, and attending the same school as the intervention class. All intervention classes had parallel classes. We chose to do the follow-up at six months so that the control group could receive the intervention in the same school year (after data collection was completed). This made it easier for us to convince schools to participate.

Participants

Eligibility criteria

Students aged 10 to 15 attending grades six to eight of a secondary general, intermediate, grammar, or comprehensive school are eligible. Older or younger students or students from other school types are not. Schools in Gießen and the surrounding area already participate in the programme each year. They know that participation is voluntary and can be ended at any time without giving a reason. The geographical area concerned (Gießen and surrounding villages) was informed about the study via the Hessian Ministry of Education and Cultural Affairs.

(Figure1.tiff (stored separately))

Intervention

The programme consists of two 60-minute modules. The first part is 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 consists of an interactive PowerPoint presentation in which the participants are encouraged to make their own well-informed decisions and receive relevant knowledge on handling confrontations with their peers (social competence approach). The university hospital patient with a smoking-related disease is interviewed about his reasons to start smoking and the influence tobacco consumption had on his life. The participants are encouraged to ask the patient questions. The second part takes place in an interactive classroom setting in which two medical students (usually a male and a female) tutor one class. Both modules focus 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). The participants also

discuss information relevant for their age group, e.g., why non-smokers look usually more attractive, have more money to buy things, or are in better physical shape. The programme focuses on not scaring but educating its participants in an interactive manner. EAT uses a combined social influences and social competences approach, which was described as the most effective approach in the recently published Cochrane Analysis [14].

Data collection

A written survey questionnaire is used for the collection of the data. The questionnaire was developed to collect data at both time points (t1-t2). In addition to the socio-demographic data (age, gender, school type), it will capture the smoking status of the school students concerning water pipe and cigarette consumption. ~~To maximize the external validity of the intervention, the questionnaires will be placed in envelopes which are instantly being sealed by the responsible class teachers immediately after completion.~~

The questionnaire contains numerous items which have already been included in similar investigations. The questions about the smoking status and the frequency of smoking refer to the evaluation of the school-based smoking prevention programmes in Heidelberg entitled “ohne kippe” (no butts) [22] and in Berlin entitled “Students in the hospital” [14] as well as to the results of the KiGGs child and adolescent surveys published by Lampert and Thamm [23].

To test the questionnaire in accordance to the GEP guidelines [24], we distributed 88 copies to pupils with the lowest education level in May 2013. 85 of the completed questionnaires were deemed as a useful way for evaluation, but seven had not been filled out completely. Therefore, we added a note to turn the page at the bottom of

each page to fix this problem.

The class teachers will individually supervise their classes during the completion of the questionnaire. To maximize the confidentiality of the intervention, the questionnaires will be placed in envelopes which are instantly being sealed by the responsible class teachers immediately after completion. The envelopes will be opened and the data entry and analysis will be performed under the supervision of Prof. Dr. Groneberg at the Goethe University of Frankfurt.

~~**Data management and analysis**~~

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Participants and sample size

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Legal approval

In accordance with Good Epidemiologic Practice (GEP) guidelines [24], the study protocol was submitted for approval by the responsible ethics committee, which decided that the study does not need ethical approval (ethics committee of Goethe University, Frankfurt-Main, Germany). All legal and data protection issues were discussed with the responsible authority, the Ministry of Education and Cultural Affairs in Germany, which approved the proposed data collection within the participating schools. In addition, each school individually discussed and approved the study at a school conference. It was explained to each student that participation is voluntarily, and informed written consent was obtained from the parents of the study participants.

Sample Size Calculation

As there is no other evaluated school-based programme delivered by medical students, our study has an explorative character. Still, we decided to calculate the sample size (using the

programme BiAS for Windows) on the basis of a recently published study which evaluated the "Non-smoking is Cool" school-based physician delivered programme in Hamburg [18]. To calculate the sample based on effect size requirements, we used the difference in the number of persons who started smoking within nine months between the intervention and control group at grammar schools investigated in the reference study (6.4% in the intervention group vs. 12% in the control group yields a difference of 5.6%) [16]. We decided to use the method of Sack et al. for our calculations because "Students in the Hospital" mainly included school types with a lower educational level. We used the rates for grammar school students, who will be the largest group of participants in our study. Thus, we calculated that the required sample size is 435 pupils per group (870 total), plus the loss to follow-up group at a test power of 80% (alpha = 0.05). We took into account the loss to follow-up effect of "Students in the Hospital" (17,8%), which increased our group size to n1 = 514 and n2 = 514 (total: 1028) [15].

(Figure1.tiff (stored seperately))

Gender specific aspects

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Outcomes

The primary outcome is the prevalence of smokers and non-smokers at 6 months after the intervention. The primary endpoint is the percentage difference between smokers and non-smokers in the two study arms at baseline and 6 months after the intervention (lifetime prevalence). The percentage of former smokers and new smokers in the two groups and the measures of smoking behaviour (the number of cigarettes and water pipes smoked on a daily, weekly or monthly basis) will be studied as secondary outcome measures. A smoker is defined as a pupil who claims to smoke at least “once a month” within the survey. Those pupils who claim not to

smoke at all are defined as non-smokers. In accordance to their answers within the survey, non-smokers will be divided in “former smokers” and in “non-smokers who have never smoked before”.

Statistical analysis

Sample Size Calculation

As there is no other evaluated school-based programme delivered by medical students, our study has an explorative character. Still, we decided to calculate the sample size (using the programme BiAS for Windows) on the basis of a recently published study which evaluated the “Non-smoking is Cool” school-based physician delivered programme in Hamburg [18]. To calculate the sample based on effect size requirements, we used the difference in the number of persons who started smoking within nine months between the intervention and control group at grammar schools investigated in the reference study (6.4% in the intervention group vs. 12% in the control group yields a difference of 5.6%) [16]. We decided to use the method of Sack et al. for our calculations because ”Students in the Hospital” mainly included school types with a lower educational level. We used the rates for grammar school students, who will be the largest group of participants in our study. Thus, we calculated that the required sample size is 435 pupils per group (870 total), plus the loss to follow-up group at a test power of 80% (alpha = 0.05). We took into account the loss to follow-up effect of “Students in the Hospital” (17,8%), which increased our group size to n1 = 514 and n2 = 514 (total: 1028) [15].

Analysis

In order to examine baseline differences of pupils’ characteristics in our quasi-experimental design we will use χ^2-tests for the categorical variables and t-tests for

continuous variables. There must be no significant differences between the two study groups at baseline (t1). The effects of predictors (like gender, culture and social characteristics) on the smoking behaviour after six months (t2) will be calculated by logistic regression analysis, a state-of-the-art technique for the evaluation of the effectiveness of prevention programmes [22, 25, 26] in longitudinal studies. The significance level is 5% for t-tests (double-sided) and 95% for confidence intervals (double-sided). The statistical analysis will be performed using the newest version of SPSS Statistics for Mac by IBM.

Legal approval

In accordance with Good Epidemiologic Practice (GEP) guidelines [24], the study protocol was submitted for approval by the responsible ethics committee, which decided that the study does not need ethical approval (ethics committee of Goethe University, Frankfurt-Main, Germany). All legal and data protection issues were discussed with the responsible authority, the Ministry of Education and Cultural Affairs in Germany, which approved the proposed data collection within the participating schools. In addition, each school individually discussed and approved the study at a school conference. It was explained to each student that participation is voluntarily, and informed written consent was obtained from the parents of the study participants.

Discussion

~~Strengths and limitations~~

No evaluation of a medical student-delivered school-based tobacco prevention programme is available to date. It is imperative to sensitize prospective physicians to tobacco prevention [13]. An additional aim of this study is to evaluate whether a medical student-delivered smoking prevention program has preventive effects on the smoking behaviour of secondary school pupils in Germany. The data from this study will provide a sound basis for optimizing the Education Against Tobacco curriculum to make it optimally effective for different target groups. A promising factor of the EAT programme is that it uses a combined social influence and social competence approach, which was been shown to be effective in the recently published Cochrane Analysis [14].

Our study has a quasi-experimental design. The main problem of this kind of study is selection bias due to the lack of randomization. To minimize this problem, we will match the intervention classes with ~~parallel~~ control classes (same grade and school), which corresponds to the matching procedure in field experiments.

As the intervention and control groups attend the same schools, the pupils could exchange what they learn about smoking in the intervention during school breaks. Therefore cluster effects cannot be excluded entirely.

Also, as our research is not multi-national, it might not be useful for persons of all ethnic and cultural backgrounds.

Because our study relies on self-reports obtained from adolescents via a questionnaire for data collection, there is a risk that the actual prevalence of smoking may be different from the reported prevalence, e.g. due to social desirability bias. This bias can only be excluded by using expensive methods like testing for cotinine (a metabolite of nicotine) in the saliva, blood or urine of the students. Other alternatives described by Ketala et al. (2004) include the measurement of

thiocyanate in saliva or carbon monoxide in exhaled air [27]. This group reported 95% agreement between the results of these biochemical tests and the results of questionnaires. Conversely, Connor Gorber et al. (2009) found high differences between biochemically assessed and self-reported smoking status in pregnant women and patients with tobacco-related diseases [28]. In our study, there might be social desirability bias in both study groups, which might make the intervention look less effective than it actually is:

The first measurement at baseline occurs while the intervention group is anticipating the intervention. Therefore, more intervention group students might feel compelled to behave in a socially desirable way and falsely declare that they are non-smokers. In contrast, the control group students know that they will not see the medical students again anytime soon, so they might be inclined to answer more honestly to the items on the questionnaire. At the second measurement time point, the situation is reversed: Because the intervention group students know that the medical students will not come back, they might feel less social desirability pressure and be more likely to admit that they are smokers. In contrast, the control group students will be awaiting the next intervention in the coming weeks, so they might reply to the questionnaires in a more socially desired way (declaring that they are non-smokers even if they smoke).

Consequently, the study could be compromised by social desirability bias at both time points, which could make the intervention look less effective.

In order to measure the long-term effects of school-based programmes, follow-up data is usually collected six months and one year after an intervention. However, we will only be able to collect data six months post-intervention because the schools

insisted on us providing an intervention for the control group in the same school year. Thus, we will not be able to determine which effects the intervention might have at one year follow-up.

Conclusion

We expect that our research will find general acceptance because the investigated programme provides many medical students and even more medical interns (e.g., in the elective period known) a great opportunity to deliver prevention programmes not only in inpatient secondary prevention, but also and in particular in primary prevention in schools and communities. Health systems worldwide could benefit from the development of such novel and low-cost primary smoking prevention programmes.

Authors' contributions

TJB contributed to the design and conduct of the study, drafted the manuscript, and will perform the statistical analysis. WS supports the coordination of the study. SS-B contributed to the design of the study, participated in the writing process, and proofread the manuscript. DAG contributed to the design of the study 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 pays a small fee for the copies of the questionnaire that are

being distributed to every participating student. There are no other funding sources available.

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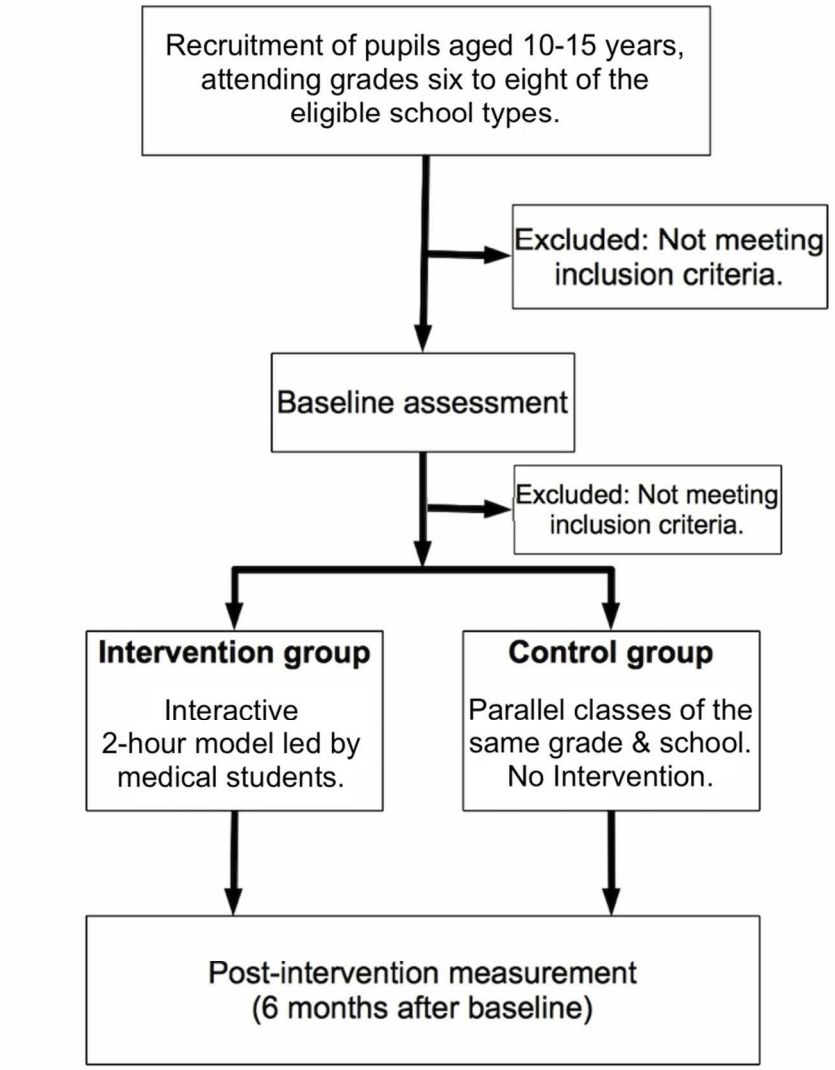

Figure 1
Study design.

87x124mm (300 x 300 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.