



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

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5 **Education Against Tobacco (EAT) - Evaluation of a school-based program for**
6 **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

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3 as a direct result of this intervention. We will optimize the curriculum on the basis of
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5 the results of this evaluation to make it optimally effective for both genders and
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7 different ethnic groups.
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10 11 **Strengths and limitations of this study**

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14 A consequence of our research is suspected to be the general acceptance that
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16 medical students and even more medical interns (PJ-medical students) offer a great
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18 opportunity to deliver prevention programs. Therefore, health systems worldwide may
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20 largely benefit from the development of a novel and low-cost measure of primary
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22 prevention. A main limitation would be the fact that our research is not been done
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24 multinationally and therefore might not be representative for every ethnical and
25
26 cultural background. Futhermore, the case and the control groups were in the same
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28 schools which is a potential confounding variable as the pupils could exchange what
29
30 they have learned about smoking due to the intervention during the school breaks.
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36 **Keywords:** smoking prevention, school-based prevention, primary prevention,
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38 medical students, schools, adolescents
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44 **Background**

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46 Tobacco consumption is a risk factor for various diseases and leads to the highest
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48 number of avoidable deaths worldwide [1]. Despite warning labels and public
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50 interventions, smoking causes diseases and death in Germany where it was
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52 responsible for almost 107.000 deaths in 2007 [2, 3]. In addition, it generates high
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54 financial costs. A study which modelled the costs of productivity losses due to
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56 smoking in Germany for the year 2005 [3] calculated productivity costs of 9.6 billion
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3 Euro which were caused by smoking. Most smokers started smoking in early
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5 adolescence [4]. In a survey conducted and published by the Federal Centre for
6
7 Health Education (Bundeszentrale für gesundheitliche Aufklärung, BZgA) in Germany
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9 in 2012 35.2% of all young adults (18 to 25 years) and 12.0% of all adolescents (12
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11 to 17 years) described themselves as regular cigarette smokers [5]. Furthermore, in
12
13 the past few years there was an increase in the use of water pipes [6]. According to a
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15 survey conducted by the Federal Centre for Health Education in 2011, 8.7% of
16
17 adolescents and 11.2% of the participating young adults had smoked water pipe at
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19 least once in the 30 days leading up to the survey [6]. Male respondents have
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21 smoked water pipe more frequently than women [6]. According to Maziak, water
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23 pipes lead the way to cigarette smoking and have similarly deleterious effects for
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25 human health [7].
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31 A survey conducted in 2006 quantified nicotine dependency with the help of the
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33 Fagerström test [8]. It reported that 50.8% of the 15– to 17-year-old smokers and
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35 41.8% of those in the 18– to 24-year age group were dependent on nicotine. Laucht
36
37 and Schmid reported a correlation between the number of cigarettes smoked and the
38
39 starting age in 15-year-old adolescents [9]. It was demonstrated that the earlier in life
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41 they had smoked their first cigarette, the more likely they were still consuming
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43 tobacco, the more cigarettes they were currently consuming and the higher was their
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45 degree of dependence.
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50 Early primary prevention of smoking is thus of crucial importance and therefore
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52 should be promoted, evaluated and optimized.
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55 **School-based smoking prevention program**

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3 The registered association „education against tobacco“ (hereinafter referred to as
4 "EAT") has been founded and developed since August 2011 by medical student Titus
5 Brinker of the University of Gießen in cooperation with professors from the
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7 Universities of Gießen, Frankfurt and Marburg as well as fellow students from the
8
9 Texas A&M University. The program has been developed taking into account the
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11 Cochrane Database Systematic Review on school-based programmes for preventing
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13 smoking (2006)(13) in regard of its conclusion to focus on the development of low
14
15 cost prevention programs and its implication for research to combine social
16
17 influences approaches with generic social competence approaches. Both of these
18
19 key points have been taken into account when developing the EAT curriculum. At the
20
21 time of development there was already research available which encouraged EAT to
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23 use medical students as Sussman et al [10] concluded that health educator-led drug
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25 prevention programs are more effective than self-instructed programs.
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33 Since physician-based programs have proven to be successful [12] but usually are
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35 very expensive, we aim to evaluate and optimize the widespread low-cost program
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37 “education against tobacco“ which is being delivered by about 400 medical students
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39 at 16 universities in Germany. The city of Gießen provides an excellent platform to
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41 evaluate this effect as it homes the largest EAT group with the highest experience
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43 level and the most participating EAT schools.
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48 **Objectives**

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51 In the past years, prevention science has emerged as a research discipline built on
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53 the integration of life course development research, community epidemiology, and
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55 preventive intervention trials. Our objective is to integrate these aspects in order to
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3 promote prevention in the area of tobacco addiction with a focus on low cost
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5 widespread programs.
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8 We plan to evaluate the effect on the smoking behavior of the curriculum being
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10 delivered by medical students in order to reach a sound basis for a future, nation-
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12 wide program. In this connection, we consider gender, social, and cultural aspects of
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14 the intervention in order to optimize the curriculum which includes the design of an
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16 evidence-based and easy to implement train the trainer EAT program as a
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18 consequence of this study by engulfing recent research knowledge on smoking
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20 related diseases. By doing this, we plan to improve the education of the health
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22 educators (participating medical students) by the use of additional expert knowledge
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24 on the topic. This train the trainer program also sensitizes the medical students –
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26 regardless of their future medical specialization – towards the needs of tobacco
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28 prevention and thus increases the knowledge on prevention among the future
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30 physicians.
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36 Consequently, it is our strategy to perpetuate the program on a national level by
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38 developing a system for the integration of EAT into the structure of medical faculties
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40 and large teaching hospitals. In this respect, we will customize the project for an
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42 integration of EAT into elective courses (Wahlfächer) or cross sectional areas
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44 (Querschnittsbereiche) such as prevention (QB10) or environmental medicine (QB6)
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46 at the medical schools of the 16 EAT partner universities.
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50 **Methods**

51 **Study design and setting**

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3 The survey will be designed as a prospective case-control study with quasi-
4 experimental design. We could not afford randomization as it includes a huge
5 organizational and personal effort we were not capable to perform. In addition, some
6 classes would not agree to participate within the study when they would be
7 predetermined as control groups which became clear in advance of the investigation.
8 To keep confounding factors to a minimum, the parallel class of intervention classes
9 in a given grade is selected for the control group. To maximize the external validity of
10 the intervention, the questionnaires will be put into envelopes which are instantly
11 being sealed by the responsible class teachers after completion. The teachers sign a
12 brief declaration where they state to be fully responsible for the sealing process
13 directly after the questionnaires have been filled out by the pupils. The envelopes will
14 be opened and the data evaluation will be performed under the supervision of Prof.
15 Dr. Groneberg at the Goethe University Frankfurt. The class teachers individually
16 supervise their classes for the completion of the questionnaire.
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35 For the collection of the data we will use a written survey in the form of a
36 questionnaire. This questionnaire is developed to collect data to each of the defined
37 time points (t1-t2). In addition to the socio-demographic data (age, gender, school
38 type), we will obtain the smoking status of the school students concerning water pipe
39 and cigarettes.
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48 The questionnaire will contain numerous items which have already been a part of
49 similar investigations. The questions about the smoking status and the frequency of
50 smoking refer to the evaluation of the school-based smoking prevention program
51 from Heidelberg „ohne Kippe“ [13] and the publication of Lampert and Thamm [14]
52 about the results of the child and adolescent surveys (KiGGS).
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3 The period of time of the survey is planned to be from October 2013 until July of
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5 2014. Participants in two study groups (intervention by medical students and control)
6
7 will be questioned up to 2 weeks in advance of the intervention (t1) and 6 months
8
9 thereafter (t2) (see Figure 1).
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11 To test the questionnaire in accordance to the GEP guidelines [15], we carried out 88
12
13 copies to pupils with the lowest education level participating in May 2013. We
14
15 investigated that 85 of these questionnaires were filled out in a useful way for
16
17 evaluation. However, seven pupils did not fill out the questionnaire completely. We
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19 added a notification to turn the page at the bottom of each page to fix this problem.
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24 **Participants and Sample Size**

25 *Eligibility criteria*

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28 Students aged 10 to 15 attending a secondary general, intermediate, grammar, or
29
30 comprehensive school are eligible. The schools in Gießen and the surrounding cities
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32 are already involved in the program and let their classes participate every year.
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35 Participation is voluntary and could be ended at any time without giving a reason.
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40 *Legal approval*

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43 In accordance to Good Epidemiologic Practice (GEP) guidelines[15], approval of the
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45 responsible ethics committee was asked for and the committee decided that the
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47 study does not need ethical approval (ethics committee of the Goethe University,
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49 Frankfurt am Main, Germany). All legal preparations and data protection issues have
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51 been discussed with the responsible ministry of education and cultural affairs in
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53 Germany. The ministry gave approval for the stated proceed of data collection within
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55 the participating schools. In addition, each school individually discussed and
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3 approved the study in its schools' conference. The participation of each student was
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5 declared to be voluntarily and informed written consent was obtained from the
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7 parents of the study participants.
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10 *Sample Size Calculation*

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14 The recruitment sample was calculated on the basis of a recently published study
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16 [12] and will amount to 1.002 pupils (n1 = 501 participating in the medical students
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18 delivered intervention n2 = 501 pupils in the control group) at least at a test power of
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20 80% (alpha = 0,05). In consideration of the loss to follow-up effect, it is planned to
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22 include at least 1.200 participants (600 per group).
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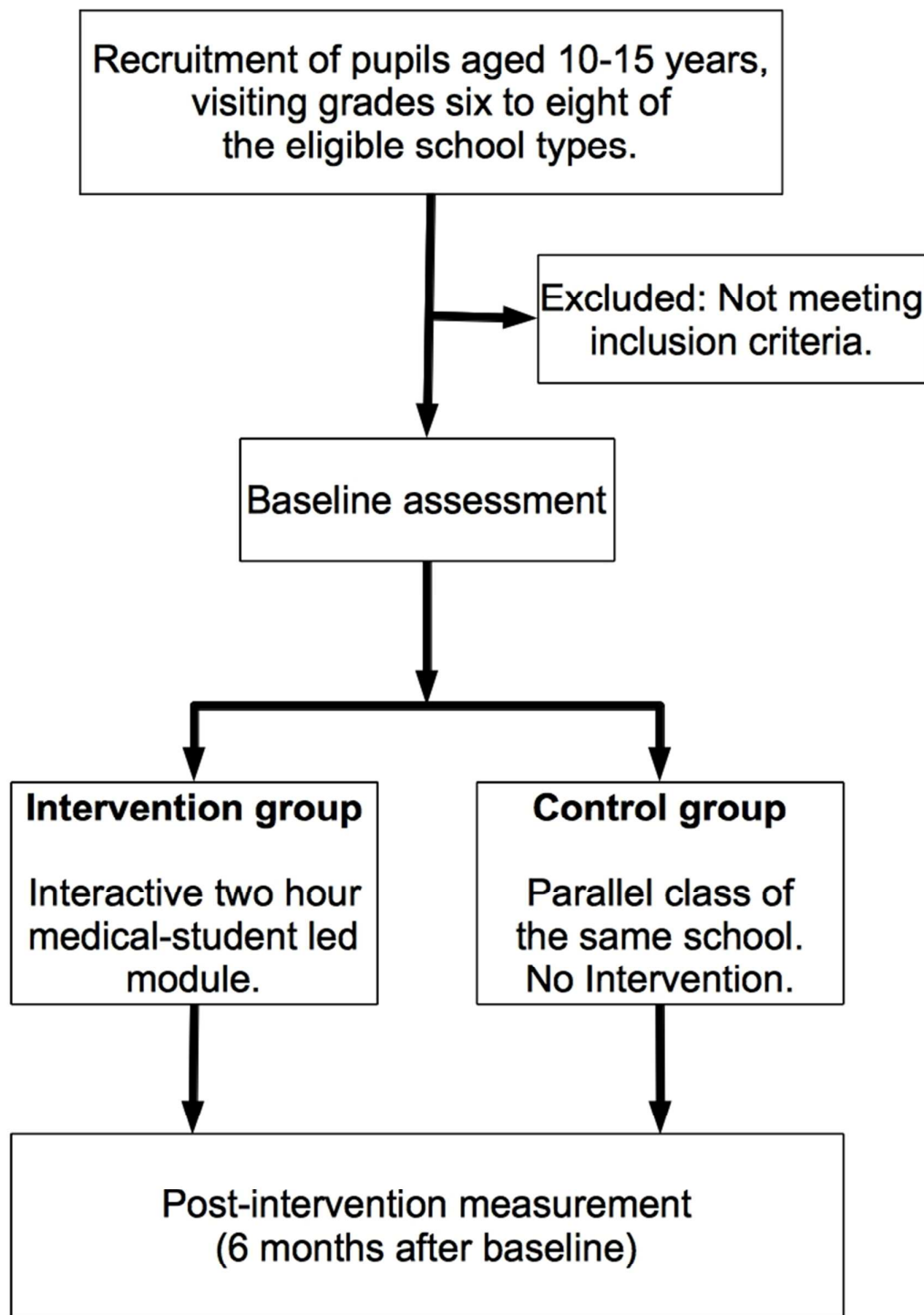


Figure 1
Study design.

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

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3 curriculum. Within the projected optimization process, the EAT curriculum can also
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5 be structured in relation to the different school populations which can be encountered
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7 (i.e. schools with a high percentage of pupils of migration background vs. schools
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9 without).
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11 12 13 **Social aspects**

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16 According to a survey conducted by the Federal Centre for Health Education [5], the
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18 prevalence of cigarette smoking in the age group of 10 to 15 year old pupils was
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20 significantly higher in schools with lower education levels in Germany in 2012 (16,7%
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22 vs. 6,9%)(16). As a consequence, we plan to specifically address schools with lower
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24 education levels and to compare the effects on different school types.
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28 29 **Outcomes**

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32 The primary endpoint is the percentage difference between smokers and non-
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34 smokers in the two study arms at baseline and 6 months after the intervention
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36 (lifetime prevalence). Measures of smoking behavior (the number of cigarettes and
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38 water pipes smoked) will be studied as secondary outcome measures.
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42 43 **Statistical analysis**

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46 In order to determine relevant effect sizes in consideration of the measurements
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48 before and after the intervention, we plan to use the χ^2 -square-test for frequency
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50 distributions. In addition, we plan to use the t-Test/the Wilcoxon-test for mean value
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52 differences of paired and unpaired samples. In order to illustrate the attitude towards
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54 smoking between the intervention groups and the control group during the time
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56 progress of the study we plan to use the univariate variance analysis. For the
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58 calculation of the predictors of the smoking behavior we use the logistic regression
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3 analysis which is the state-of-the-art technique for the evaluation of the effectiveness
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5 of prevention programs [13, 17, 18].
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7 The test for significance is planned on the 5% level (double-sided), confidence
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9 intervals for 95% (double-sided). The software for our analysis is planned to be the
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11 newest version of SPSS Statistics for Mac by IBM.
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14 **Discussion**

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18 So far, medical student delivered school-based programmes for preventing smoking
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20 have not been evaluated. Therefore, only little relevant data is available in scientific
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22 databases such as Medline or PubMed. The most relevant publication on the topic is
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24 the Cochrane Database Analysis on school-based programs for preventing smoking
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26 [19]. The authors analyzed the data from 134 studies, in 25 different countries, which
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28 included a total of 428.293 young people aged 5-18. Of these, 49 studies reported
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30 smoking behavior in those adolescents who had never previously smoked. The
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32 authors concluded that further research is required to design and test programs that
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34 will be equally effective for both genders, different cultural backgrounds and ethnic
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36 groups. Interventions delivered by adult educators were shown to be more effective
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38 in the longer term than peer-education programs. In this respect, medical students
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40 belong to the group of adult educators. According to the Cochrane Analysis, cost-
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42 effectiveness plays an important role for practical implementation. As EAT is
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44 delivered by volunteering medical students, it is less expensive but more available
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46 than physician delivered programs.
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52 The Cochrane Database Analysis did not include recently published data on school-
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54 based health educator delivered programs in Germany. Within the evaluation of the
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56 physician-based program "Students in the Hospital" in Berlin, significant positive
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58 results were present for an information-based curriculum [12].
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3 An anonymous survey by questionnaire from September 2007 to July 2008 was
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5 conducted, with a quasi-experimental control-group design, two weeks before (t1)
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7 and six months after (t2) the intervention in a group of 760 participating school
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9 students in Berlin.
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12 The results indicated that 40.8% of the participants were smokers, among whom
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14 79% stated that they also smoked water pipes. As major primary prevention outcome
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16 of the study, it was found that significantly fewer students in the intervention group
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18 than in the control group began smoking in the six months after the intervention
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20 ($p < 0.001$). In addition, the chance of remaining a non-smoker was four times as high
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22 in the intervention group (OR, 4.14; CI, 1.66–10.36). Concerning gender aspects,
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24 girls appeared to benefit more from the intervention than boys (OR 2.56, CI 1.06–
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26 6.19)(1). 16.1% of smokers in the intervention group and 17.6% in the control group
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28 stopped smoking ($p > 0.05$). Conclusively, a clear primary preventive effect of the
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30 program was demonstrated.
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36 Since physician-based programmes are usually very expensive, it is indicated to
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38 evaluate a less expensive and widespread program.
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41 **Conclusion**

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43 A consequence of our research is suspected to be the general acceptance that
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45 medical students and even more medical interns (PJ-medical students) offer a great
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47 opportunity to deliver primary prevention programs. This does not only refer to
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49 inpatient secondary prevention but especially refers to primary prevention within the
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51 community/school. Therefore, the German health system may largely benefit from
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53 the development of a novel and low-cost measure of primary prevention.
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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) <i>Case-control study</i> —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) <i>Case-control study</i> —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 <i>Case-control study</i> —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 checked (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*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure checked <i>Cross-sectional study</i> —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
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*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

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

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

- 20
21 • No medical student-delivered school-based tobacco prevention programme
22 has been evaluated for its primary preventive effect to date.
- 23
24 • It is imperative to sensitize prospective physicians to tobacco prevention.
- 25
26 • The quasi-experimental design of this study might cause a selection bias due
27 to the lack of randomization.
- 28
29 • Cluster effects cannot be excluded entirely as the control classes are located
30 in the same schools and pupils could exchange what they have learned.
- 31
32 • As our research is not multi-national, it might not be useful for persons of all
33 ethnic and cultural backgrounds.
- 34
35 • Because our study relies on self-reports obtained from adolescents via a
36 questionnaire for data collection, there is a risk that the actual prevalence of
37 smoking may be different from the reported prevalence, e.g. due to social
38 desirability bias.
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40 • Our follow-up data is only collected six months after the intervention due to
41 organisational reasons. Thus, we will not be able to determine which effects
42 the intervention might have at one year follow-up.
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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,

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2
3 evaluated and optimized.
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6 Some scientifically validated smoking prevention programmes already exist in
7
8 Germany, like the Smoke-Free Class (SFC) competition, which was shown to have a
9
10 significant primary preventive long-term effect and cost-effectiveness [10, 11].

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12 However, the SFC competition focuses only on cigarettes and not on water pipe
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14 smoking. In addition, there is no comparable beneficial effect for the instructors of the
15
16 SFC programme. Education Against Tobacco additionally sensitizes prospective
17
18 physicians to the importance of tobacco prevention. A recent study from Yale
19
20 University suggests that tobacco addiction is undertreated by physicians in
21
22 comparison to other chronic conditions [12]. The authors concluded that alternative
23
24 models of engagement may be needed to enhance use of effective treatments for
25
26 tobacco addiction and to raise awareness among physicians.
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31 To our knowledge, medical student delivered school-based programmes for
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33 preventing smoking have not been evaluated to date. Little relevant data is available
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35 in scientific databases such as Medline or PubMed. The most relevant publication on
36
37 the topic is the Cochrane Database Analysis on school-based programmes for
38
39 preventing smoking [13]. The authors analyzed the data from 134 studies in 25
40
41 different countries in a total of 428,293 young people aged 5 to 18. Forty-nine of
42
43 these studies reported smoking behaviour in adolescents who had never previously
44
45 smoked. No overall effect of intervention curricula vs. control was found based on the
46
47 pooled results at follow-up at one year or less (odds ratio [OR] 0.94, 95% confidence
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49 interval [CI] 0.85 to 1.05) [13]. From our perspective, the most relevant finding of the
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51 Cochrane Analysis is that social competence and social influence curricula have a
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53 statistically significant effect of preventing the onset of smoking [13]. The authors
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55 concluded that further research is required to design and test programmes that will
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3 be equally effective for people of different genders, cultural backgrounds and ethnic
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5 groups. Interventions delivered by adult educators were shown to be more effective
6
7 in the longer term than peer-education programmes. Medical students belong to the
8
9 group of adult educators. According to the Cochrane Analysis, cost-effectiveness
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11 plays an important role in practical implementation. As Education against Tobacco is
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13 delivered by medical student volunteers, it is less expensive and more available than
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15 physician-delivered programmes.
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19 Secondary school programmes which involve physicians as health educators already
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21 exist. In fact, Stamm-Balderjahn et al. [14] recently published data on a school-based
22
23 physician-delivered programme (Students in the Hospital) in Berlin, which achieved
24
25 significant positive results with a multimodal approach .From September 2007 to July
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27 2008, they conducted an anonymous questionnaire survey with a quasi-experimental
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29 control group design two weeks before (t1) and six months after (t2) the intervention
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31 in a group of 760 participating school students in Berlin. The results indicated that
32
33 40.8% of the participants were smokers at baseline, 79% of whom stated that they
34
35 also smoked water pipes. Regarding the primary prevention outcome of the study, it
36
37 was found that significantly fewer students in the intervention group began smoking
38
39 within six months of the intervention than in the control group ($p < 0.001$). In addition,
40
41 the chance of remaining a non-smoker was four times higher in the intervention
42
43 group (OR, 4.14; CI, 1.66–10.36). Concerning gender, girls appeared to benefit more
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45 from the intervention than boys (OR 2.56, CI 1.06–6.19). 16.1% of smokers in the
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47 intervention group and 17.6% in the control group stopped smoking ($p > 0.05$). A
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49 primary preventive effect of the programme was clearly and conclusively
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51 demonstrated.
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58 Non-smoking is Cool (NiC), another physician-delivered programme based in
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3 Hamburg, Germany, addresses grades 5 to 6 of all secondary school types (total
4 sample size reported: 1359 students) [15]. The programme uses a social influence-
5 and fear-based curriculum. Multiple studies have shown that fear-based appeals are
6 ineffective for primary tobacco prevention in the long term [16]. NiC proved to be
7 effective in grammar schools, where it reduced the onset of smoking in the
8 intervention group by 50% compared to the control group at three and nine months
9 follow-up, but with a small effect size [17]. Nevertheless, it failed to show a significant
10 primary preventive effect in schools with a lower educational level (general,
11 intermediate, or comprehensive school) [17].
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24 Considering the high cost of physician-based programmes and the lack of available
25 physicians, it is indicated to evaluate a less expensive and widespread programme
26 that sensitizes prospective physicians to tobacco prevention.
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32 **School-based smoking prevention programme delivered by medical students**

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34 Education Against Tobacco (EAT) is a non-profit, medical student-delivered school-
35 based smoking prevention programme founded in August 2011 by Titus Brinker, a
36 medical student at the University of Gießen, and developed in cooperation with
37 professors from the Universities of Gießen, Frankfurt and Marburg as well as medical
38 students from Texas A&M University. The programme takes the Cochrane Analysis
39 into account [18]. Its mission is to focus on the development of low-cost prevention
40 programmes and their implications for research, and to combine social influences
41 approaches with generic social competence approaches. Both of these key points
42 were taken into account when developing the curriculum. At the time of development,
43 there was already research available that encouraged the use of medical students in
44 such programmes. For example, Sussman et al. [19] concluded that health educator-
45 led drug prevention programmes are more effective than self-instructed programmes.
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3 Since physician-based programmes have proven to be successful [14] but usually
4 are very expensive, we aimed to evaluate and optimize Education Against Tobacco,
5 a widespread low-cost programme which is being delivered by about 400 medical
6 students at 16 universities in Germany. It costs only about EUR 25 per participating
7 class. The city of Gießen, home of the largest EAT group with the highest level of
8 experience and the most participating EAT schools, is an adequate platform to
9 evaluate the effects of EAT.
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20 Objectives

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23 1) To assess the efficacy of the programme, we investigated two main questions:
24 a. Does the EAT programme help non-smokers to remain abstinent?
25 b. Does the EAT programme encourage smokers to take steps to stop
26 smoking?
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31 2) To assess whether the programme is equally effective for participants of
32 different gender, social and cultural backgrounds, we investigated the
33 questions:
34 a. Is the EAT programme equally effective for both genders?
35 b. Is the EAT programme equally effective for different school types?
36 c. Is the EAT programme equally effective for different cultural
37 backgrounds?
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46 Methods

47 Intervention

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50 The programme consists of two 60-minute modules. The first part is presented by
51 two to six medical students and a patient with a tobacco-related disease to all pupils
52 at the same time inside a large room within the school. It consists of an interactive
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3 PowerPoint presentation in which the participants are encouraged to make their own
4 well-informed decisions and receive relevant knowledge on handling confrontations
5 with their peers (social competence approach). The university hospital patient with a
6 smoking-related disease is interviewed about his reasons to start smoking and the
7 influence tobacco consumption had on his life. The participants are encouraged to
8 ask the patient questions. The second part takes place in an interactive classroom
9 setting in which two medical students (usually a male and a female) tutor one class.
10 Both modules focus on educating adolescents about the strategies of the tobacco
11 industry to influence their decision in a non-objective manner (social influence) and
12 on peer pressure (social influence), decision-making and skills for coping with
13 challenges in their life in a healthy way (social competence). The participants also
14 discuss information relevant for their age group, e.g., why non-smokers look usually
15 more attractive, have more money to buy things, or are in better physical shape. The
16 programme focuses on not scaring but educating its participants in an interactive
17 manner. EAT uses a combined social influences and social competences approach,
18 which was described as the most effective approach in the recently published
19 Cochrane Analysis [13].
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45 **Study design and setting**

46 47 **Design**

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51 The survey is designed as a quasi-experimental prospective evaluative study with
52 two measurements (baseline and 6 months post-intervention). The planned study
53 period is October 2013 until July of 2014. Participants in two study groups
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3 (intervention and control groups) will be questioned up to 2 weeks in advance of the
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5 intervention (t1) and 6 months thereafter (t2) (see Figure 1).
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9 Randomization could not be performed due to the tremendous organizational and
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11 personal effort required for it. Some classes refused to participate when informed that
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13 they would be control groups. To keep confounding factors to a minimum, a parallel
14
15 class in a given grade was selected as the control group. All participating schools
16
17 were asked in advance to split their grades into two class-groups with the same
18
19 performance levels. Schools that did not agree to the splitting procedure were
20
21 excluded. A parallel class is defined as a control class in the same grade as the
22
23 intervention class, with the same performance level as the intervention class, and
24
25 attending the same school as the intervention class. All intervention classes had
26
27 parallel classes. We chose to do the follow-up at six months so that the control group
28
29 could receive the intervention in the same school year (after data collection was
30
31 completed). This made it easier for us to convince schools to participate.
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36 **Data collection**

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39 A written survey questionnaire is used for the collection of the data. The
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41 questionnaire was developed to collect data at both time points (t1-t2). In addition to
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43 the socio-demographic data (age, gender, school type), it will capture the smoking
44
45 status of the school students concerning water pipe and cigarette consumption. To
46
47 maximize the external validity of the intervention, the questionnaires will be placed in
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49 envelopes which are instantly being sealed by the responsible class teachers
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51 immediately after completion.
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55 **Data management and analysis**

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3 The envelopes will be opened and data analysis performed under the supervision of
4
5 Prof. Dr. Groneberg at the Goethe University of Frankfurt. The class teachers will
6
7 individually supervise their classes during the completion of the questionnaire.
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11 The questionnaire contains numerous items which have already been included in
12
13 similar investigations. The questions about the smoking status and the frequency of
14
15 smoking refer to the evaluation of the school-based smoking prevention programmes
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17 in Heidelberg entitled “Ohne Kippe” (No Butts) [20] and in Berlin entitled “Students in
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19 the hospital” [14] as well as to the results of the KiGGs child and adolescent surveys
20
21 published by Lampert and Thamm [21].
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27 To test the questionnaire in accordance to the GEP guidelines [22], we distributed 88
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29 copies to pupils with the lowest education level in May 2013. 85 of the completed
30
31 questionnaires were deemed as a useful way for evaluation, but seven had not been
32
33 filled out completely. Therefore, we added a note to turn the page at the bottom of
34
35 each page to fix this problem.
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38 39 **Participants and sample size**

40 41 *Eligibility criteria*

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46 Students aged 10 to 15 attending grades six to eight of a secondary general,
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48 intermediate, grammar, or comprehensive school are eligible. Older or younger
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50 students or students from other school types are not. Schools in Gießen and the
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52 surrounding area already participate in the programme each year. They know that
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54 participation is voluntary and can be ended at any time without giving a reason. The
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3 geographical area concerned (Gießen and surrounding villages) was informed about
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5 the study via the Hessian Ministry of Education and Cultural Affairs.
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8 9 *Legal approval*

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11 In accordance with Good Epidemiologic Practice (GEP) guidelines [22], the study
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13 protocol was submitted for approval by the responsible ethics committee, which
14
15 decided that the study does not need ethical approval (ethics committee of Goethe
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17 University, Frankfurt-Main, Germany). All legal and data protection issues were
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19 discussed with the responsible authority, the Ministry of Education and Cultural
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21 Affairs in Germany, which approved the proposed data collection within the
22
23 participating schools. In addition, each school individually discussed and approved
24
25 the study at a school conference. It was explained to each student that participation
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27 is voluntarily, and informed written consent was obtained from the parents of the
28
29 study participants.
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34 35 *Sample Size Calculation*

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37 As there is no other evaluated school-based programme delivered by medical students, our
38
39 study has an explorative character. Still, we decided to calculate the sample size (using the
40
41 programme BiAS for Windows) on the basis of a recently published study which evaluated
42
43 the “Non-smoking is Cool” school-based physician delivered programme in Hamburg [17].
44
45 To calculate the sample based on effect size requirements, we used the difference in the
46
47 number of persons who started smoking within nine months between the intervention and
48
49 control group at grammar schools investigated in the reference study (6.4% in the
50
51 intervention group vs. 12% in the control group yields a difference of 5.6%) [15]. We
52
53 decided to use the method of Sack et al. for our calculations because “Students in the
54
55 Hospital” mainly included school types with a lower educational level. We used the rates for
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3 grammar school students, who will be the largest group of participants in our study. Thus,
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5 we calculated that the required sample size is 435 pupils per group (870 total), plus the loss
6
7 to follow-up group at a test power of 80% ($\alpha = 0.05$). We took into account the loss to
8
9 follow-up effect of “Students in the Hospital” (17,8%), which increased our group size to $n_1 =$
10
11 514 and $n_2 = 514$ (total: 1028) [14].
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15 (Figure1.tiff (stored seperately))
16

17 18 19 **Gender specific aspects**

20
21 Our recent study using the physician-based approach for school-based tobacco
22
23 prevention [14] showed that girls benefit from physician-delivered programmes more
24
25 than boys (OR 2.56, CI 1.06–6.19). We aim to assess whether this effect is also
26
27 observed using the EAT medical student-based approach. If so, the programme will
28
29 be modified for gender mainstreaming since both sexes need to be addressed
30
31 equally.
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36 37 38 **Cultural aspects**

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40 We hypothesize that there will be a small but significant relation between water pipe
41
42 smoking and cultural background since water pipe use is traditional in the Middle
43
44 East region [23]. Therefore, we plan to collect data on the cultural background of the
45
46 students. Comprehensive information about water pipe smoking is an integral
47
48 component of the EAT programme. Within the proposed optimization process, the
49
50 EAT curriculum can be tailored to the different school populations (e.g., schools with
51
52 or without a high percentage of pupils with a migration background) as needed.
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55 56 57 **Social aspects**

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3 According to a survey conducted by the Federal Centre for Health Education [5], the
4 prevalence of cigarette smoking in 10- to 15-year-olds in Germany was significantly
5 higher in schools with lower education levels in 2012 (16.7% vs. 6.9%).
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10 Consequently, we plan to specifically address schools with lower education levels
11 and to compare the effects of the intervention on different school types.
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14 15 16 17 18 **Outcomes**

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

37
38 In order to examine baseline differences of pupils' characteristics in our quasi-
39 experimental design we will use χ^2 -tests for the categorical variables and t-tests for
40 continuous variables. There must be no significant differences between the two study
41 groups at baseline (t1). The effects of predictors on the smoking behaviour after six
42 months (t2) will be calculated by logistic regression analysis, a state-of-the-art
43 technique for the evaluation of the effectiveness of prevention programmes [20, 24,
44 25] in longitudinal studies. The significance level is 5% for t-tests (double-sided) and
45 95% for confidence intervals (double-sided). The statistical analysis will be performed
46 using the newest version of SPSS Statistics for Mac by IBM.
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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.

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3 This bias can only be excluded by using expensive methods like testing for cotinine
4 (a metabolite of nicotine) in the saliva, blood or urine of the students. Other
5 alternatives described by Ketala et al. (2004) include the measurement of
6 thiocyanate in saliva or carbon monoxide in exhaled air [26]. This group reported
7 95% agreement between the results of these biochemical tests and the results of
8 questionnaires. Conversely, Connor Gorber et al. (2009) found high differences
9 between biochemically assessed and self-reported smoking status in pregnant
10 women and patients with tobacco-related diseases [27]. In our study, there might be
11 social desirability bias in both study groups, which might make the intervention look
12 less effective than it actually is:
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26 The first measurement at baseline occurs while the intervention group is anticipating
27 the intervention. Therefore, more intervention group students might feel compelled to
28 behave in a socially desirable way and falsely declare that they are non-smokers. In
29 contrast, the control group students know that they will not see the medical students
30 again anytime soon, so they might be inclined to answer more honestly to the items
31 on the questionnaire. At the second measurement time point, the situation is
32 reversed: Because the intervention group students know that the medical students
33 will not come back, they might feel less social desirability pressure and be more likely
34 to admit that they are smokers. In contrast, the control group students will be
35 awaiting the next intervention in the coming weeks, so they might reply to the
36 questionnaires in a more socially desired way (declaring that they are non-smokers
37 even if they smoke).
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54 Consequently, the study could be compromised by social desirability bias at both
55 time points, which could make the intervention look less effective.
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3 In order to measure the long-term effects of school-based programmes, follow-up
4 data is usually collected six months and one year after an intervention. However, we
5 will only be able to collect data six months post-intervention because the schools
6 insisted on us providing an intervention for the control group in the same school year.
7 Thus, we will not be able to determine which effects the intervention might have at
8 one year follow-up.
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16 17 **Conclusion**

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

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41 TJB contributed to the design and conduct of the study, drafted the manuscript, and
42 will perform the statistical analysis. WS supports the coordination of the study. SS-B
43 contributed to the design of the study, participated in the writing process, and
44 proofread the manuscript. DAG contributed to the design of the study and proofread
45 the manuscript. All authors read and approved the final manuscript. This study is part
46 of a thesis project (TJB).
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56 **Competing interests:**

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58 The authors declare that they have no competing interests.
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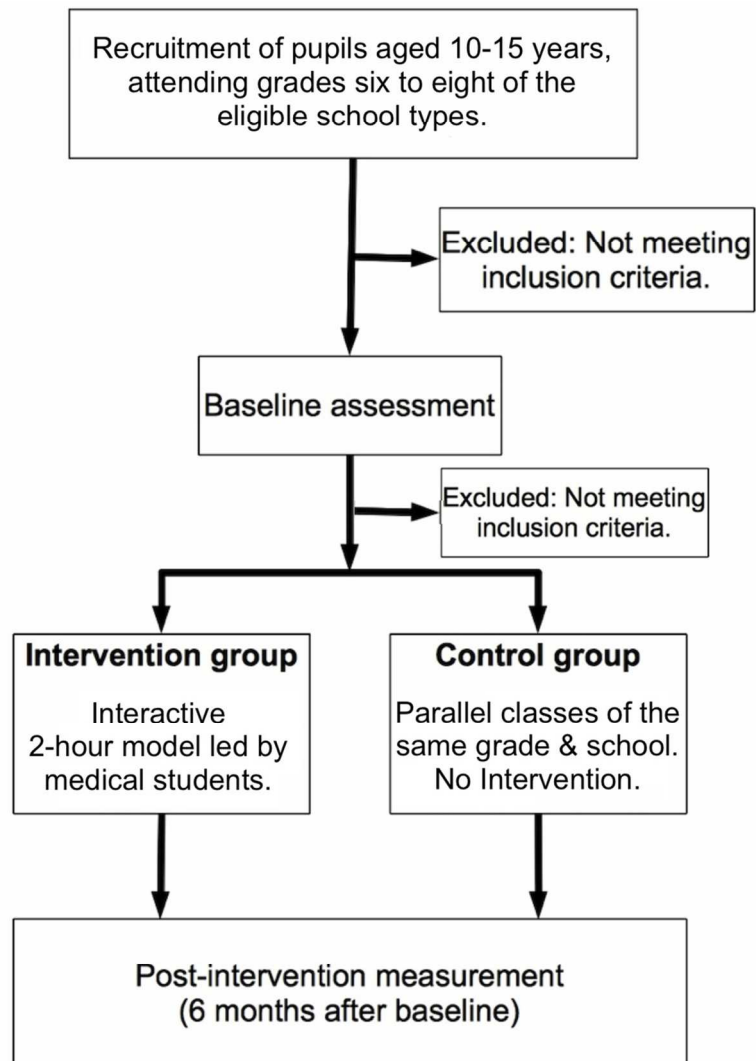


Figure 1
Study design.

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**Education ~~Against-against~~ Tobacco (EAT) - A quasi-experimental prospective
eEvaluation 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.~~

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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.

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~~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]. 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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7 was demonstrated that the earlier in life they had smoked their first cigarette, the
8 more likely they were still consuming tobacco, the more cigarettes they were
9 currently consuming and the higher was their degree of dependence.
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12 Furthermore, in the past few years there was an increase in the use of water pipes
13 [8]. According to a survey conducted by the Federal Centre for Health Education in
14 2011, 8.7% of adolescents and 11.2% of the participating young adults had smoked
15 water pipe at least once in the 30 days leading up to the survey [8]. Male
16 respondents have smoked water pipe more frequently than women [8]. According to
17 Maziak, water pipes lead the way to cigarette smoking and have similarly deleterious
18 effects for human health [9].
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27 Early primary prevention of smoking is thus of crucial importance and therefore
28 should be promoted, evaluated and optimized.
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32 There are already scientifically evaluated prevention programs in Germany available
33 like the smokefree class competition (SFC) which has shown a significant primary
34 preventive long-term effect and cost-effectiveness [10, 11]. However, the SFC
35 competition focusses on cigarette consumption exclusively and does not include
36 waterpipe smoking. In addition, there is no comparable beneficiary effect for the
37 instructors of the SFC program. In contrast, EAT additionally sensitizes prospective
38 physicians for the importance of tobacco prevention. As a recent study from Yale
39 University suggests, tobacco addiction is undertreated by physicians in comparison
40 to other chronic conditions [12]. The authors concluded, that alternate models of
41 engagement may be needed to enhance use of effective treatments for tobacco
42 addiction and to rise the awareness among physicians.
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54 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)

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

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11 The results indicated that 40.8% of the participants were smokers at baseline, among
12 whom 79% stated that they also smoked water pipes. As major primary prevention
13 outcome of the study, it was found that significantly fewer students in the intervention
14 group than in the control group began smoking in the six months after the
15 intervention (p<0.001). In addition, the chance of remaining a non-smoker was four
16 times as high in the intervention group (OR, 4.14; CI, 1.66–10.36). Concerning
17 gender aspects, girls appeared to benefit more from the intervention than boys (OR
18 2.56, CI 1.06–6.19)(1). 16.1% of smokers in the intervention group and 17.6% in the
19 control group stopped smoking (p>0.05). Conclusively, a clear primary preventive
20 effect of the program was demonstrated.

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

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33 Nevertheless, in schools with a lower educational level (general, intermediate, or
34 comprehensive school) it failed to show a significant primary preventive effect [17].

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

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School-based smoking prevention program delivered by medical students

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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.

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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

per participating class. The city of Gießen provides an excellent useful platform to evaluate this effect as it homes the largest EAAAT group with the highest experience level and the most participating EAAAT 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, nationwide 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

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7 room setting with two medical students tutoring one class (usually a male and a
8 female). Both parts educate the adolescents about the strategies of the tobacco
9 industry to influence their decision in an unobjectice manner (social influence), about
10 peer pressure (social influence), decision making and about skills how they can deal
11 with challenges in their life in a healthy way (social competence). In addition, the
12 participants discuss relevant information for their age group e.g. why nonsmokers
13 look usually more attractive, have more money to buy things or are in better shape
14 for physical education. The program focusses on not scaring but educating its
15 participants in an interactive manner. Consequently, the EAT program uses a
16 combined social influences and social competences curriculum which has been
17 shown to be the most effective approach in the recently published Cochrane Analysis
18 [13].
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33 **Study design and setting**

34 Design

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39 The survey will be designed as a quasi-experimental prospective evaluative study
40 including 2 measures (at baseline and 6 months after intervention)prospective case-
41 control-study with quasi-experimental design. The period of time of the survey is
42 planned to be from October 2013 until July of 2014. Participants in two study groups
43 (intervention by medical students and control) will be questioned up to 2 weeks in
44 advance of the intervention (t1) and 6 months thereafter (t2) (see Figure 1).
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51 We could not afford randomization as it includes a huge organizational and personal
52 effort we were not capable to perform. In addition, some classes would not agree to
53 participate within the study when they would be predetermined as control groups
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7 which became clear in advance of the investigation. To keep confounding factors to a
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9 minimum, the parallel class of intervention classes in a given grade is selected for the
10 control group. All participating schools were asked in advance to split their grades
11 into two class-groups with the same performance level on their own. Schools who
12 would not agree with the splitting were excluded. Parallel classes are defined as
13 control classes which are in the same grade as the intervention class, have the same
14 performance level as the intervention class and visit the same school as the
15 intervention class. Consequently, all classes have parallel classes. In addition, we
16 chose to do the follow-up after six months so the control group could receive the
17 intervention in the same school year (after data collection is complete) which made it
18 easier for us to cooperate with the schools.

Data collection

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

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

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53 ~~To maximize the external validity of the intervention, the questionnaires will be put~~
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7 after completion. The envelopes will be opened and the data evaluation will be
8 performed under the supervision of Prof. Dr. Groneberg at the Goethe University
9 Frankfurt. The class teachers individually supervise their classes for the completion
10 of the questionnaire.
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15 For the collection of the data we will use a written survey in the form of a
16 questionnaire. This questionnaire is developed to collect data to each of the defined
17 time points (t1-t2). In addition to the socio-demographic data (age, gender, school
18 type), we will obtain the smoking status of the school students concerning water pipe
19 and cigarettes. The teachers sign a brief declaration where they state to be fully
20 responsible for the sealing process directly after the questionnaires have been filled
21 out by the pupils. **Data management and analysis**
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30 The envelopes will be opened and the data evaluation will be performed under the
31 supervision of Prof. Dr. Groneberg at the Goethe University of Frankfurt. The class
32 teachers individually supervise their classes for the completion of the questionnaire.
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36 The questionnaire will contain numerous items which have already been a part of
37 [similar](#) investigations. The questions about the smoking status and the frequency of
38 smoking refer to the evaluation of the school-based smoking prevention program
39 from Heidelberg „ohne Kippe“ [18] and the publication of Lampert and Thamm [21]
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44 about the results of the child and adolescent surveys (KiGGS).
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49 ~~The period of time of the survey is planned to be from October 2013 until July of~~
50 ~~2014. Participants in two study groups (intervention by medical students and control)~~
51 ~~will be questioned up to 2 weeks in advance of the intervention (t1) and 6 months~~
52 ~~thereafter (t2) (see Figure 1).~~
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7 To test the questionnaire in accordance to the GEP guidelines [22], we carried out 88
8 copies to pupils with the lowest education level participating in May 2013. We
9 investigated that 85 of these questionnaires were filled out in a useful way for
10 evaluation. However, seven pupils did not fill out the questionnaire completely. We
11 added a notification to turn the page at the bottom of each page to fix this problem.
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16 17 **Participants and Sample Size**

18 19 *Eligibility criteria*

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22 Students aged 10 to 15 attending grades six to eight of a secondary general,
23 intermediate, grammar, or comprehensive school are eligible. Older or younger
24 students, or students from other school types are persons who do not meet the
25 inclusion criteria. The schools in Gießen and the surrounding cities are already
26 involved in the program and let their classes participate every year. Participation is
27 voluntary and could be ended at any time without giving a reason. The geographical
28 area concerned (Gießen and surrounding villages) was informed via the ministry of
29 cultural affairs in Hessen, Germany.
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39 40 *Legal approval*

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42 In accordance to Good Epidemiologic Practice (GEP) guidelines [22], approval of the
43 responsible ethics committee was asked for and the committee decided that the
44 study does not need ethical approval (ethics committee of the Goethe University,
45 Frankfurt am Main, Germany). All legal preparations and data protection issues have
46 been discussed with the responsible ministry of education and cultural affairs in
47 Germany. The ministry gave approval for the stated proceed of data collection within
48 the participating schools. In addition, each school individually discussed and
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7 approved the study in its schools' conference. The participation of each student was
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9 declared to be voluntarily and informed written consent was obtained from the
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11 parents of the study participants.

12 13 *Sample Size Calculation*

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

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47 ((Figure 1.tiff (stored separately))We did not calculate the sample size for the reason
48 of the explorative character of the study. The recruitment sample was calculated on
49 the basis of a recently published study [14] and will amount to 1.002 pupils (n1 = 501
50 participating in the medical students delivered intervention n2 = 501 pupils in the
51 control group) at least at a test power of 80% (alpha = 0,05). In consideration of the
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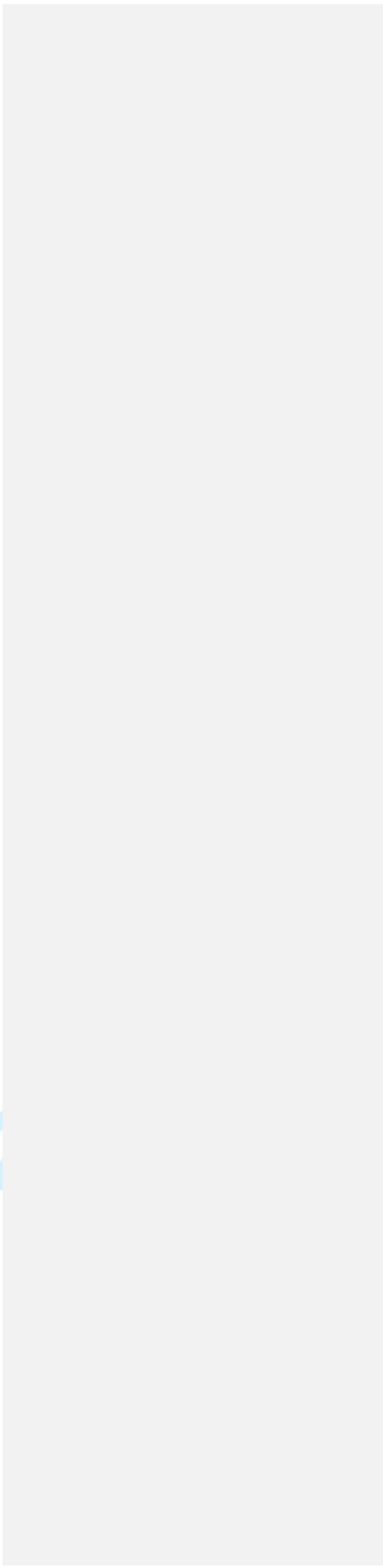
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loss to follow up effect, it is planned to include at least 1.200 participants (600 per group).

For peer review only



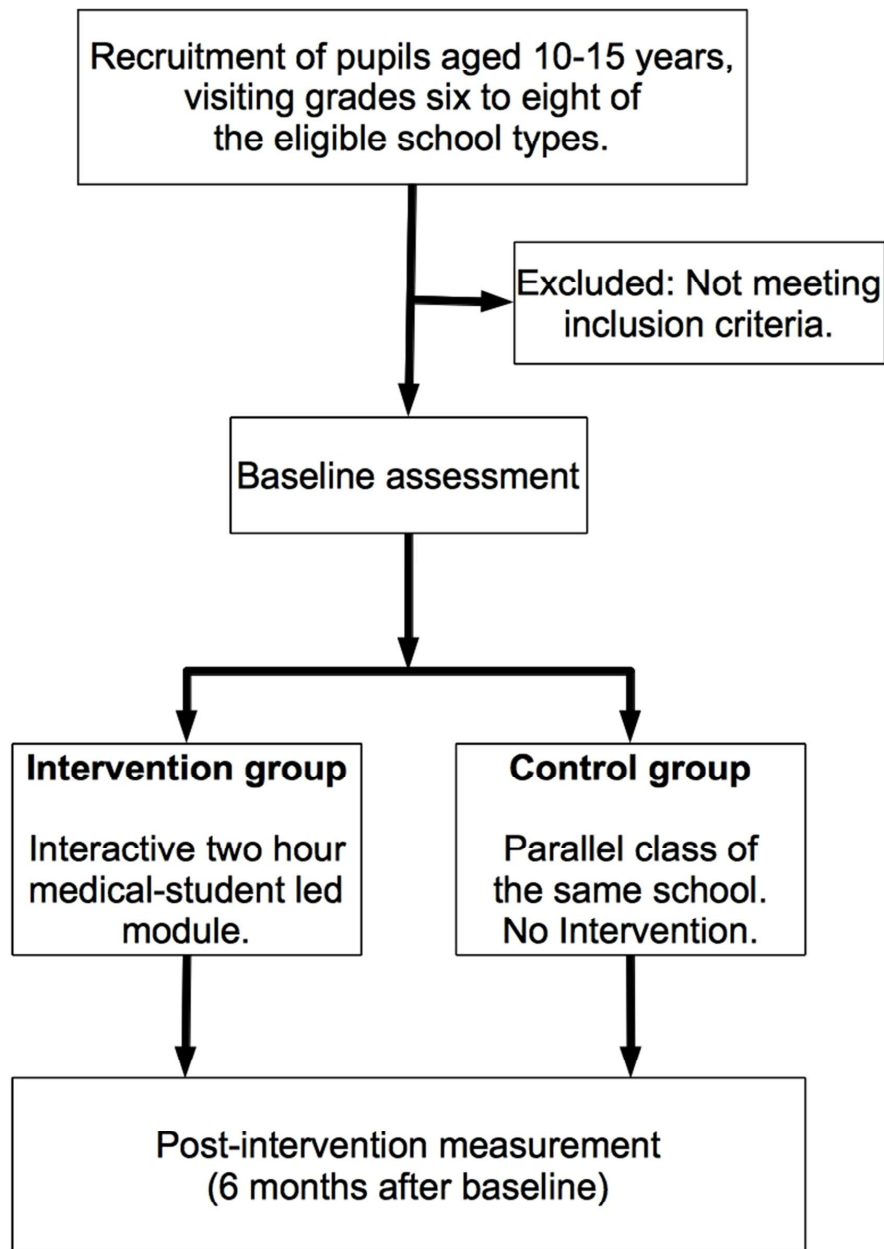


Figure 1
Study design.

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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 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 [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

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7 curriculum. Within the projected optimization process, the EAT curriculum can also
8 be structured in relation to the different school populations which can be encountered
9 (i.e. schools with a high percentage of pupils of migration background vs. schools
10 without).
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14 15 **Social aspects**

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17 According to a survey conducted by the Federal Centre for Health Education [5], the
18 prevalence of cigarette smoking in the age group of 10 to 15 year old pupils was
19 significantly higher in schools with lower education levels in Germany in 2012 (16,7%
20 vs. 6,9%)(16). As a consequence, we plan to specifically address schools with lower
21 education levels and to compare the effects on different school types.
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28 29 **Outcomes**

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31 The primary endpoint is the percentage difference between smokers and non-
32 smokers in the two study arms at baseline and 6 months after the intervention
33 (lifetime prevalence). The percentage of former smokers and new smokers in the two
34 two groups and the m Measures of smoking behavior (the number of cigarettes and
35 water pipes smoked on a daily, weekly or monthly basis) will be studied as secondary
36 outcome measures. ~~We adata concerning~~
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44 45 **Statistical analysis**

46 In order to examine baseline differences of pupils' characteristics in our quasi-
47 experimental design we will use χ^2 -tests for the categorical variables and t-tests for
48 continuous variables. No significant differences are aloud between the two study
49 groups at baseline (t1). For the calculation of the effects predictors have on the
50 smoking behavior after six months (t2) we use the logistic regression analysis which
51 is the state-of-the-art technique for the evaluation of the effectiveness of prevention
52 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.~~

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~~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~~

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~~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.~~

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~~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~~

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~~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~~

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~~studies.~~

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~~Our significance level for t-tests is 5% (double-sided) and for confidence intervals~~

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~~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

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~~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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7 whether medical student delivered prevention programs in addition have preventive
8 effects on the smoking behaviour of secondary school pupils in Germany. The data
9 of this study gives us a sound basis for optimizing the EAT curriculum to be optimally
10 effective for different target groups. A promising factor of the EAT program is that it
11 uses a combined social influence and social competence curriculum which has been
12 shown to be effective in the recently published Cochrane Analysis [13].

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

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

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

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

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7 insisted on providing an intervention for the control group in the same school year.

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9 Thus, it remains unclear which effects the intervention would show after one year
10 follow-up.

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

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

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54 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 systems worldwide 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) <i>Case-control study</i> —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) <i>Case-control study</i> —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 <i>Case-control study</i> —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 checked (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*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure checked <i>Cross-sectional study</i> —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
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*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

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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Keywords:	smoking prevention, schools, tobacco prevention, medical students, adolescent smoking, school-based prevention

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5 **Education Against Tobacco (EAT) - A quasi-experimental prospective**
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7 **evaluation of a programme for preventing smoking in secondary schools**
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9 **delivered by medical students: a study protocol**
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14 Titus J. Brinker^{1*}, Sabine Stamm-Balderjahn², Werner Seeger³, David A. Groneberg¹
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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.

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

- 20
21 • No medical student-delivered school-based tobacco prevention programme
22 has been evaluated for its primary preventive effect to date.
- 23
24 • It is imperative to sensitize prospective physicians to tobacco prevention.
- 25
26 • The quasi-experimental design of this study might cause a selection bias due
27 to the lack of randomization.
- 28
29 • Cluster effects cannot be excluded entirely as the control classes are located
30 in the same schools and pupils could exchange what they have learned.
- 31
32 • As our research is not multi-national, it might not be useful for persons of all
33 ethnic and cultural backgrounds.
- 34
35 • Because our study relies on self-reports obtained from adolescents via a
36 questionnaire for data collection, there is a risk that the actual prevalence of
37 smoking may be different from the reported prevalence, e.g. due to social
38 desirability bias.
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40 • Our follow-up data is only collected six months after the intervention due to
41 organisational reasons. Thus, we will not be able to determine which effects
42 the intervention might have at one year follow-up.
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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,

1
2
3 evaluated and optimized.

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6 Some scientifically evaluated smoking prevention programmes already exist in
7
8 Germany, like the Smoke-Free Class (SFC) competition which has been practically
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10 implemented in many countries of the European Union [10-12]. However, the only
11
12 study of the SFC competition which reported a significant effect on the prevention of
13
14 smoking at the longest follow-up had multiple biases according to the recent
15
16 Cochrane Database Systematic Review on incentives for preventing smoking in
17
18 adolescents by Johnston et al. [12]. In addition, Johnston et al. calculated the
19
20 adjusted relative risk (RR) of the study and no longer detected a statistically
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22 significant difference [12]. Finally, the authors concluded that there are no incentive
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24 programmes available to date which have shown to prevent smoking initiation among
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26 youth [12].
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31 In addition to that, the SFC competition focuses only on cigarettes and not on water
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33 pipe smoking. Furthermore, there is no comparable beneficial effect for the
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35 instructors of the SFC programme. Education Against Tobacco additionally sensitizes
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37 prospective physicians to the importance of tobacco prevention. A recent study from
38
39 Yale University suggests that tobacco addiction is undertreated by physicians in
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41 comparison to other chronic conditions [13]. The authors concluded that alternative
42
43 models of engagement may be needed to enhance use of effective treatments for
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45 tobacco addiction and to raise awareness among physicians.
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50 To our knowledge, medical student delivered school-based programmes for
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52 preventing smoking have not been evaluated to date. Little relevant data is available
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54 in scientific databases such as Medline or PubMed. The most relevant publication on
55
56 the topic is the Cochrane Database Analysis on school-based programmes for
57
58 preventing smoking [14]. The authors analyzed the data from 134 studies in 25
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3 different countries in a total of 428,293 young people aged 5 to 18. Forty-nine of
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5 these studies reported smoking behaviour in adolescents who had never previously
6
7 smoked. No overall effect of intervention curricula vs. control was found based on the
8
9 pooled results at follow-up at one year or less (odds ratio [OR] 0.94, 95% confidence
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11 interval [CI] 0.85 to 1.05) [14]. From our perspective, the most relevant finding of the
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13 Cochrane Analysis is that social competence and social influence curricula have a
14
15 statistically significant effect of preventing the onset of smoking [14]. The authors
16
17 concluded that further research is required to design and test programmes that will
18
19 be equally effective for people of different genders, cultural backgrounds and ethnic
20
21 groups. Interventions delivered by adult educators were shown to be more effective
22
23 in the longer term than peer-education programmes. Medical students belong to the
24
25 group of adult educators. According to the Cochrane Analysis, cost-effectiveness
26
27 plays an important role in practical implementation. As Education against Tobacco is
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29 delivered by medical student volunteers, it is less expensive and more available than
30
31 physician-delivered programmes.
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38 Secondary school programmes which involve physicians as health educators already
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40 exist. In fact, Stamm-Balderjahn et al. [15] recently published data on a school-based
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42 physician-delivered programme (Students in the Hospital) in Berlin, which achieved
43
44 significant positive results with a multimodal approach .From September 2007 to July
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46 2008, they conducted an anonymous questionnaire survey with a quasi-experimental
47
48 control group design two weeks before (t1) and six months after (t2) the intervention
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50 in a group of 760 participating school students in Berlin. The results indicated that
51
52 40.8% of the participants were smokers at baseline, 79% of whom stated that they
53
54 also smoked water pipes. Regarding the primary prevention outcome of the study, it
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56 was found that significantly fewer students in the intervention group began smoking
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3 within six months of the intervention than in the control group ($p < 0.001$). In addition,
4
5 the chance of remaining a non-smoker was four times higher in the intervention
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7 group (OR, 4.14; CI, 1.66–10.36). Concerning gender, girls appeared to benefit more
8
9 from the intervention than boys (OR 2.56, CI 1.06–6.19). 16.1% of smokers in the
10
11 intervention group and 17.6% in the control group stopped smoking ($p > 0.05$). A
12
13 primary preventive effect of the programme was clearly and conclusively
14
15 demonstrated.
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19 Non-smoking is Cool (NiC), another physician-delivered programme based in
20
21 Hamburg, Germany, addresses grades 5 to 6 of all secondary school types (total
22
23 sample size reported: 1359 students) [16]. The programme uses a social influence-
24
25 and fear-based curriculum. Multiple studies have shown that fear-based appeals are
26
27 ineffective for primary tobacco prevention in the long term [17]. NiC proved to be
28
29 effective in grammar schools, where it reduced the onset of smoking in the
30
31 intervention group by 50% compared to the control group at three and nine months
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33 follow-up, but with a small effect size [18]. Nevertheless, it failed to show a significant
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35 primary preventive effect in schools with a lower educational level (general,
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37 intermediate, or comprehensive school) [18].
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43 Considering the high cost of physician-based programmes and the lack of available
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45 physicians, it is indicated to evaluate a less expensive and widespread programme
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47 that sensitizes prospective physicians to tobacco prevention.
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50 **Gender specific aspects**

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54 Our recent study using the physician-based approach for school-based tobacco
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56 prevention [15] showed that girls benefit from physician-delivered programmes more
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58 than boys (OR 2.56, CI 1.06–6.19). We aim to assess whether this effect is also
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3 observed using the EAT medical student-based approach. If so, the programme will
4
5 be modified for gender mainstreaming since both sexes need to be addressed
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7 equally.
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10 **Cultural aspects**

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13 We hypothesize that there will be a small but significant relation between water pipe
14
15 smoking and cultural background since water pipe use is traditional in the Middle
16
17 East region [19]. Therefore, we plan to collect data on the cultural background of the
18
19 students. Comprehensive information about water pipe smoking is an integral
20
21 component of the EAT programme. Within the proposed optimization process, the
22
23 EAT curriculum can be tailored to the different school populations (e.g., schools with
24
25 or without a high percentage of pupils with a migration background) as needed.
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30 **Social aspects**

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33 According to a survey conducted by the Federal Centre for Health Education [5], the
34
35 prevalence of cigarette smoking in 10- to 15-year-olds in Germany was significantly
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37 higher in schools with lower education levels in 2012 (16.7% vs. 6.9%).
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41 Consequently, we plan to specifically address schools with lower education levels
42
43 and to compare the effects of the intervention on different school types.
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46 **School-based smoking prevention programme delivered by medical students**

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48 Education Against Tobacco (EAT) is a non-profit, medical student-delivered school-
49
50 based smoking prevention programme founded in August 2011 by Titus Brinker, a
51
52 medical student at the University of Gießen, and developed in cooperation with
53
54 professors from the Universities of Gießen, Frankfurt and Marburg as well as medical
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56 students from Texas A&M University. The programme takes the Cochrane Analysis
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3 into account [20]. Its mission is to focus on the development of low-cost prevention
4 programmes and their implications for research, and to combine social influences
5 approaches with generic social competence approaches. Both of these key points
6 were taken into account when developing the curriculum. At the time of development,
7 there was already research available that encouraged the use of medical students in
8 such programmes. For example, Sussman et al. [21] concluded that health educator-
9 led drug prevention programmes are more effective than self-instructed programmes.
10
11 Since physician-based programmes have proven to be successful [15] but usually
12 are very expensive, we aimed to evaluate and optimize Education Against Tobacco,
13 a widespread low-cost programme which is being delivered by about 400 medical
14 students at 16 universities in Germany. It costs only about EUR 25 per participating
15 class. The city of Gießen, home of the largest EAT group with the highest level of
16 experience and the most participating EAT schools, is an adequate platform to
17 evaluate the effects of EAT.
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37 Objectives

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40 1) To assess the efficacy of the programme, we investigated two main questions:
41 a. Does the EAT programme help non-smokers to remain abstinent?
42 b. Does the EAT programme encourage smokers to take steps to stop
43 smoking?
44
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48 2) To assess whether the programme is equally effective for participants of
49 different gender, social and cultural backgrounds, we investigated the
50 questions:
51 a. Is the EAT programme equally effective for both genders?
52 b. Is the EAT programme equally effective for different school types?
53 c. Is the EAT programme equally effective for different cultural
54 backgrounds?
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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

1
2
3 Students aged 10 to 15 attending grades six to eight of a secondary general,
4 intermediate, grammar, or comprehensive school are eligible. Older or younger
5 students or students from other school types are not. Schools in Gießen and the
6 surrounding area already participate in the programme each year. They know that
7 participation is voluntary and can be ended at any time without giving a reason. The
8 geographical area concerned (Gießen and surrounding villages) was informed about
9 the study via the Hessian Ministry of Education and Cultural Affairs.
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20 (Figure1.tiff (stored separately))
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22 **Intervention**

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26 The programme consists of two 60-minute modules. The first part is presented by
27 two to six medical students and a patient with a tobacco-related disease to all pupils
28 at the same time inside a large room within the school. It consists of an interactive
29 PowerPoint presentation in which the participants are encouraged to make their own
30 well-informed decisions and receive relevant knowledge on handling confrontations
31 with their peers (social competence approach). The university hospital patient with a
32 smoking-related disease is interviewed about his reasons to start smoking and the
33 influence tobacco consumption had on his life. The participants are encouraged to
34 ask the patient questions. The second part takes place in an interactive classroom
35 setting in which two medical students (usually a male and a female) tutor one class.
36
37 Both modules focus on educating adolescents about the strategies of the tobacco
38 industry to influence their decision in a non-objective manner (social influence) and
39 on peer pressure (social influence), decision-making and skills for coping with
40 challenges in their life in a healthy way (social competence). The participants also
41 discuss information relevant for their age group, e.g., why non-smokers look usually
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3 more attractive, have more money to buy things, or are in better physical shape. The
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5 programme focuses on not scaring but educating its participants in an interactive
6
7 manner. EAT uses a combined social influences and social competences approach,
8
9 which was described as the most effective approach in the recently published
10
11 Cochrane Analysis [14].
12
13

14 15 **Data collection**

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17
18 A written survey questionnaire is used for the collection of the data. The
19
20 questionnaire was developed to collect data at both time points (t1-t2). In addition to
21
22 the socio-demographic data (age, gender, school type), it will capture the smoking
23
24 status of the school students concerning water pipe and cigarette consumption.
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29 The questionnaire contains numerous items which have already been included in
30
31 similar investigations. The questions about the smoking status and the frequency of
32
33 smoking refer to the evaluation of the school-based smoking prevention programmes
34
35 in Heidelberg entitled “ohne kippe” (no butts) [22] and in Berlin entitled “Students in
36
37 the hospital” [14] as well as to the results of the KiGGs child and adolescent surveys
38
39 published by Lampert and Thamm [23].
40
41

42 To test the questionnaire in accordance to the GEP guidelines [24], we distributed 88
43
44 copies to pupils with the lowest education level in May 2013. 85 of the completed
45
46 questionnaires were deemed as a useful way for evaluation, but seven had not been
47
48 filled out completely. Therefore, we added a note to turn the page at the bottom of
49
50 each page to fix this problem.
51
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54 The class teachers will individually supervise their classes during the completion of
55
56 the questionnaire. To maximize the confidentiality of the intervention, the
57
58 questionnaires will be placed in envelopes which are instantly being sealed by the
59
60

1
2
3 responsible class teachers immediately after completion. The envelopes will be
4
5 opened and the data entry and analysis will be performed under the supervision of
6
7 Prof. Dr. Groneberg at the Goethe University of Frankfurt.
8
9

10 **Outcomes**

11
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13
14 The primary outcome is the prevalence of smokers and non-smokers at 6 months
15
16 after the intervention. The percentage of former smokers and new smokers in the two
17
18 groups and the measures of smoking behaviour (the number of cigarettes and water
19
20 pipes smoked on a daily, weekly or monthly basis) will be studied as secondary
21
22 outcome measures. A smoker is defined as a pupil who claims to smoke at least
23
24 “once a month” within the survey. Those pupils who claim not to smoke at all are
25
26 defined as non-smokers. In accordance to their answers within the survey, non-
27
28 smokers will be divided in “former smokers” and in “non-smokers who have never
29
30 smoked before”.
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35 **Statistical analysis**

36 *Sample Size Calculation*

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40
41 As there is no other evaluated school-based programme delivered by medical students, our
42
43 study has an explorative character. Still, we decided to calculate the sample size (using the
44
45 programme BiAS for Windows) on the basis of a recently published study which evaluated
46
47 the “Non-smoking is Cool” school-based physician delivered programme in Hamburg [18].
48
49 To calculate the sample based on effect size requirements, we used the difference in the
50
51 number of persons who started smoking within nine months between the intervention and
52
53 control group at grammar schools investigated in the reference study (6.4% in the
54
55 intervention group vs. 12% in the control group yields a difference of 5.6%) [16]. We
56
57 decided to use the method of Sack et al. for our calculations because “Students in the
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3 Hospital” mainly included school types with a lower educational level. We used the rates for
4
5 grammar school students, who will be the largest group of participants in our study. Thus,
6
7 we calculated that the required sample size is 435 pupils per group (870 total), plus the loss
8
9 to follow-up group at a test power of 80% (alpha = 0.05). We took into account the loss to
10
11 follow-up effect of “Students in the Hospital” (17,8%), which increased our group size to $n_1 =$
12
13 514 and $n_2 = 514$ (total: 1028) [15].
14
15

16 17 *Analysis*

18
19 In order to examine baseline differences of pupils’ characteristics in our quasi-
20
21 experimental design we will use χ^2 -tests for the categorical variables and t-tests for
22
23 continuous variables. There must be no significant differences between the two study
24
25 groups at baseline (t1). The effects of predictors (like gender, culture and social
26
27 characteristics) on the smoking behaviour after six months (t2) will be calculated by
28
29 logistic regression analysis, a state-of-the-art technique for the evaluation of the
30
31 effectiveness of prevention programmes [22, 25, 26] in longitudinal studies. The
32
33 significance level is 5% for t-tests (double-sided) and 95% for confidence intervals
34
35 (double-sided). The statistical analysis will be performed using the newest version of
36
37 SPSS Statistics for Mac by IBM.
38
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43 **Legal approval**

44
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46 In accordance with Good Epidemiologic Practice (GEP) guidelines [24], the study
47
48 protocol was submitted for approval by the responsible ethics committee, which
49
50 decided that the study does not need ethical approval (ethics committee of Goethe
51
52 University, Frankfurt-Main, Germany). All legal and data protection issues were
53
54 discussed with the responsible authority, the Ministry of Education and Cultural
55
56 Affairs in Germany, which approved the proposed data collection within the
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1
2
3 participating schools. In addition, each school individually discussed and approved
4
5 the study at a school conference. It was explained to each student that participation
6
7 is voluntarily, and informed written consent was obtained from the parents of the
8
9 study participants.
10

11 12 13 14 **Discussion**

15
16
17 No evaluation of a medical student-delivered school-based tobacco prevention
18
19 programme is available to date. It is imperative to sensitize prospective physicians to
20
21 tobacco prevention [13]. An additional aim of this study is to evaluate whether a
22
23 medical student-delivered smoking prevention program has preventive effects on the
24
25 smoking behaviour of secondary school pupils in Germany. The data from this study
26
27 will provide a sound basis for optimizing the Education Against Tobacco curriculum to
28
29 make it optimally effective for different target groups. A promising factor of the EAT
30
31 programme is that it uses a combined social influence and social competence
32
33 approach, which was been shown to be effective in the recently published Cochrane
34
35 Analysis [14].
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40 Our study has a quasi-experimental design. The main problem of this kind of study is
41
42 selection bias due to the lack of randomization. To minimize this problem, we will
43
44 match the intervention classes with control classes (same grade and school), which
45
46 corresponds to the matching procedure in field experiments.
47

48
49 As the intervention and control groups attend the same schools, the pupils could
50
51 exchange what they learn about smoking in the intervention during school breaks.
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53
54 Therefore cluster effects cannot be excluded entirely.
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56
57 Also, as our research is not multi-national, it might not be useful for persons of all
58
59 ethnic and cultural backgrounds.
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3 Because our study relies on self-reports obtained from adolescents via a
4 questionnaire for data collection, there is a risk that the actual prevalence of smoking
5 may be different from the reported prevalence, e.g. due to social desirability bias.
6
7

8
9 This bias can only be excluded by using expensive methods like testing for cotinine
10 (a metabolite of nicotine) in the saliva, blood or urine of the students. Other
11 alternatives described by Ketala et al. (2004) include the measurement of
12 thiocyanate in saliva or carbon monoxide in exhaled air [27]. This group reported
13 95% agreement between the results of these biochemical tests and the results of
14 questionnaires. Conversely, Connor Gorber et al. (2009) found high differences
15 between biochemically assessed and self-reported smoking status in pregnant
16 women and patients with tobacco-related diseases [28]. In our study, there might be
17 social desirability bias in both study groups, which might make the intervention look
18 less effective than it actually is:
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33 The first measurement at baseline occurs while the intervention group is anticipating
34 the intervention. Therefore, more intervention group students might feel compelled to
35 behave in a socially desirable way and falsely declare that they are non-smokers. In
36 contrast, the control group students know that they will not see the medical students
37 again anytime soon, so they might be inclined to answer more honestly to the items
38 on the questionnaire. At the second measurement time point, the situation is
39 reversed: Because the intervention group students know that the medical students
40 will not come back, they might feel less social desirability pressure and be more likely
41 to admit that they are smokers. In contrast, the control group students will be
42 awaiting the next intervention in the coming weeks, so they might reply to the
43 questionnaires in a more socially desired way (declaring that they are non-smokers
44 even if they smoke).
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3 Consequently, the study could be compromised by social desirability bias at both
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5 time points, which could make the intervention look less effective.
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7

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9 In order to measure the long-term effects of school-based programmes, follow-up
10
11 data is usually collected six months and one year after an intervention. However, we
12
13 will only be able to collect data six months post-intervention because the schools
14
15 insisted on us providing an intervention for the control group in the same school year.
16
17 Thus, we will not be able to determine which effects the intervention might have at
18
19 one year follow-up.
20
21

22 23 **Conclusion**

24
25 We expect that our research will find general acceptance because the investigated
26
27 programme provides many medical students and even more medical interns (e.g., in
28
29 the elective period known) a great opportunity to deliver prevention programmes not
30
31 only in inpatient secondary prevention, but also and in particular in primary
32
33 prevention in schools and communities. Health systems worldwide could benefit from
34
35 the development of such novel and low-cost primary smoking prevention
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37 programmes.
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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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5 **Education Against Tobacco (EAT) - A quasi-experimental prospective**
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7 **evaluation of a programme for preventing smoking in secondary schools**
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9 **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.

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

- 20
21 • No medical student-delivered school-based tobacco prevention programme
22 has been evaluated for its primary preventive effect to date.
- 23
24 • It is imperative to sensitize prospective physicians to tobacco prevention.
- 25
26 • The quasi-experimental design of this study might cause a selection bias due
27 to the lack of randomization.
- 28
29 • Cluster effects cannot be excluded entirely as the control classes are located
30 in the same schools and pupils could exchange what they have learned.
- 31
32 • As our research is not multi-national, it might not be useful for persons of all
33 ethnic and cultural backgrounds.
- 34
35 • Because our study relies on self-reports obtained from adolescents via a
36 questionnaire for data collection, there is a risk that the actual prevalence of
37 smoking may be different from the reported prevalence, e.g. due to social
38 desirability bias.
- 39
40 • Our follow-up data is only collected six months after the intervention due to
41 organisational reasons. Thus, we will not be able to determine which effects
42 the intervention might have at one year follow-up.
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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,

1
2
3 evaluated and optimized.
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6 Some scientifically ~~validated~~-evaluated smoking prevention programmes already
7
8 exist in Germany, like the Smoke-Free Class (SFC) competition, ~~which was shown to~~
9
10 ~~have a significant primary preventive long term effect and cost effectiveness~~ which
11
12 has been practically implemented in many countries of the European Union [10-12].
13
14 However, the only study of the SFC competition which reported a significant effect on
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16 the prevention of smoking at the longest follow-up had multiple biases according to
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18 the recent Cochrane Database Systematic Review on incentives for preventing
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20 smoking in adolescents by Johnston et al. [12]. In addition, Johnston et al. calculated
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22 the adjusted relative risk (RR) of the study and no longer detected a statistically
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24 significant difference [12]. Finally, the authors concluded that there are no incentive
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26 programmes available to date which have shown to prevent smoking initiation among
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28 youth [12].
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32 In addition to that, However, the SFC competition focuses only on cigarettes and not
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34 on water pipe smoking. ~~Furthermore~~In addition, there is no comparable beneficial
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36 effect for the instructors of the SFC programme. Education Against Tobacco
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38 additionally sensitizes prospective physicians to the importance of tobacco
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40 prevention. A recent study from Yale University suggests that tobacco addiction is
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42 undertreated by physicians in comparison to other chronic conditions [13]. The
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44 authors concluded that alternative models of engagement may be needed to
45
46 enhance use of effective treatments for tobacco addiction and to raise awareness
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48 among physicians.
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54 To our knowledge, medical student delivered school-based programmes for
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56 preventing smoking have not been evaluated to date. Little relevant data is available
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58 in scientific databases such as Medline or PubMed. The most relevant publication on
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3 the topic is the Cochrane Database Analysis on school-based programmes for
4 preventing smoking [14]. The authors analyzed the data from 134 studies in 25
5
6 different countries in a total of 428,293 young people aged 5 to 18. Forty-nine of
7
8 these studies reported smoking behaviour in adolescents who had never previously
9
10 smoked. No overall effect of intervention curricula vs. control was found based on the
11
12 pooled results at follow-up at one year or less (odds ratio [OR] 0.94, 95% confidence
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14 interval [CI] 0.85 to 1.05) [14]. From our perspective, the most relevant finding of the
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16 Cochrane Analysis is that social competence and social influence curricula have a
17
18 statistically significant effect of preventing the onset of smoking [14]. The authors
19
20 concluded that further research is required to design and test programmes that will
21
22 be equally effective for people of different genders, cultural backgrounds and ethnic
23
24 groups. Interventions delivered by adult educators were shown to be more effective
25
26 in the longer term than peer-education programmes. Medical students belong to the
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28 group of adult educators. According to the Cochrane Analysis, cost-effectiveness
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30 plays an important role in practical implementation. As Education against Tobacco is
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32 delivered by medical student volunteers, it is less expensive and more available than
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34 physician-delivered programmes.
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41 Secondary school programmes which involve physicians as health educators already
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43 exist. In fact, Stamm-Balderjahn et al. [15] recently published data on a school-based
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45 physician-delivered programme (Students in the Hospital) in Berlin, which achieved
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47 significant positive results with a multimodal approach .From September 2007 to July
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49 2008, they conducted an anonymous questionnaire survey with a quasi-experimental
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51 control group design two weeks before (t1) and six months after (t2) the intervention
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53 in a group of 760 participating school students in Berlin. The results indicated that
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55 40.8% of the participants were smokers at baseline, 79% of whom stated that they
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3 also smoked water pipes. Regarding the primary prevention outcome of the study, it
4
5 was found that significantly fewer students in the intervention group began smoking
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7 within six months of the intervention than in the control group ($p < 0.001$). In addition,
8
9 the chance of remaining a non-smoker was four times higher in the intervention
10
11 group (OR, 4.14; CI, 1.66–10.36). Concerning gender, girls appeared to benefit more
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13 from the intervention than boys (OR 2.56, CI 1.06–6.19). 16.1% of smokers in the
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15 intervention group and 17.6% in the control group stopped smoking ($p > 0.05$). A
16
17 primary preventive effect of the programme was clearly and conclusively
18
19 demonstrated.
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24 Non-smoking is Cool (NiC), another physician-delivered programme based in
25
26 Hamburg, Germany, addresses grades 5 to 6 of all secondary school types (total
27
28 sample size reported: 1359 students) [16]. The programme uses a social influence-
29
30 and fear-based curriculum. Multiple studies have shown that fear-based appeals are
31
32 ineffective for primary tobacco prevention in the long term [17]. NiC proved to be
33
34 effective in grammar schools, where it reduced the onset of smoking in the
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36 intervention group by 50% compared to the control group at three and nine months
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38 follow-up, but with a small effect size [18]. Nevertheless, it failed to show a significant
39
40 primary preventive effect in schools with a lower educational level (general,
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42 intermediate, or comprehensive school) [18].
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47 Considering the high cost of physician-based programmes and the lack of available
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49 physicians, it is indicated to evaluate a less expensive and widespread programme
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51 that sensitizes prospective physicians to tobacco prevention.
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Gender specific aspects

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

17 Cultural aspects

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

37 Social aspects

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

53 **School-based smoking prevention programme delivered by medical students**

55 Education Against Tobacco (EAT) is a non-profit, medical student-delivered school-
56 based smoking prevention programme founded in August 2011 by Titus Brinker, a
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3 medical student at the University of Gießen, and developed in cooperation with
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5 professors from the Universities of Gießen, Frankfurt and Marburg as well as medical
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7 students from Texas A&M University. The programme takes the Cochrane Analysis
8
9 into account [20]. Its mission is to focus on the development of low-cost prevention
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11 programmes and their implications for research, and to combine social influences
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13 approaches with generic social competence approaches. Both of these key points
14
15 were taken into account when developing the curriculum. At the time of development,
16
17 there was already research available that encouraged the use of medical students in
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19 such programmes. For example, Sussman et al. [21] concluded that health educator-
20
21 led drug prevention programmes are more effective than self-instructed programmes.
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26 Since physician-based programmes have proven to be successful [15] but usually
27
28 are very expensive, we aimed to evaluate and optimize Education Against Tobacco,
29
30 a widespread low-cost programme which is being delivered by about 400 medical
31
32 students at 16 universities in Germany. It costs only about EUR 25 per participating
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34 class. The city of Gießen, home of the largest EAT group with the highest level of
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36 experience and the most participating EAT schools, is an adequate platform to
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38 evaluate the effects of EAT.
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43 **Objectives**

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47 1) To assess the efficacy of the programme, we investigated two main questions:
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49 a. Does the EAT programme help non-smokers to remain abstinent?
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51 b. Does the EAT programme encourage smokers to take steps to stop
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53 smoking?
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56 2) To assess whether the programme is equally effective for participants of
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58 different gender, social and cultural backgrounds, we investigated the
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60 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,

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3 ~~which was described as the most effective approach in the recently published~~
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5 ~~Cochrane Analysis [14].~~
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10 ~~Study design and setting~~

11 ~~Design~~ 12 Design

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18 The survey is designed as a quasi-experimental prospective evaluative study with
19 two measurements (baseline and 6 months post-intervention). The planned study
20 period is October 2013 until July of 2014. Participants in two study groups
21 (intervention and control groups) will be questioned up to 2 weeks in advance of the
22 intervention (t1) and 6 months thereafter (t2) (see Figure 1).
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30 Randomization could not be performed due to the tremendous organizational and
31 personal effort required for it. Some classes refused to participate when informed that
32 they would be control groups. To keep confounding factors to a minimum, a parallel
33 class in a given grade was selected as the control group. All participating schools
34 were asked in advance to split their grades into two class-groups with the same
35 performance levels. Schools that did not agree to the splitting procedure were
36 excluded. A parallel class is defined as a control class in the same grade as the
37 intervention class, with the same performance level as the intervention class, and
38 attending the same school as the intervention class. All intervention classes had
39 parallel classes. We chose to do the follow-up at six months so that the control group
40 could receive the intervention in the same school year (after data collection was
41 completed). This made it easier for us to convince schools to participate.
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57 Participants

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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

~~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) [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.~~

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 [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 $n_1 = 514$ and $n_2 = 514$ (total: 1028) [15].

(Figure1.tiff (stored seperately))

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

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

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

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41 The primary outcome is the prevalence of smokers and non-smokers at 6 months
42 after the intervention. The primary endpoint is the percentage difference between
43 smokers and non-smokers in the two study arms at baseline and 6 months after the
44 intervention (lifetime prevalence). The percentage of former smokers and new
45 smokers in the two groups and the measures of smoking behaviour (the number of
46 cigarettes and water pipes smoked on a daily, weekly or monthly basis) will be
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55 studied as secondary outcome measures. A smoker is defined as a pupil who claims
56 to smoke at least "once a month" within the survey. Those pupils who claim not to
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3 smoke at all are defined as non-smokers. In accordance to their answers within the
4 survey, non-smokers will be divided in “former smokers” and in “non-smokers who
5 have never smoked before”.
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14 **Statistical analysis**

17 Sample Size Calculation

19
20 As there is no other evaluated school-based programme delivered by medical students, our
21 study has an explorative character. Still, we decided to calculate the sample size (using the
22 programme BiAS for Windows) on the basis of a recently published study which evaluated
23 the “Non-smoking is Cool” school-based physician delivered programme in Hamburg [18].
24 To calculate the sample based on effect size requirements, we used the difference in the
25 number of persons who started smoking within nine months between the intervention and
26 control group at grammar schools investigated in the reference study (6.4% in the
27 intervention group vs. 12% in the control group yields a difference of 5.6%) [16]. We
28 decided to use the method of Sack et al. for our calculations because “Students in the
29 Hospital” mainly included school types with a lower educational level. We used the rates for
30 grammar school students, who will be the largest group of participants in our study. Thus,
31 we calculated that the required sample size is 435 pupils per group (870 total), plus the loss
32 to follow-up group at a test power of 80% (alpha = 0.05). We took into account the loss to
33 follow-up effect of “Students in the Hospital” (17,8%), which increased our group size to n1 =
34 514 and n2 = 514 (total: 1028) [15].
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54 Analysis

56 In order to examine baseline differences of pupils' characteristics in our quasi-
57 experimental design we will use χ^2 -tests for the categorical variables and t-tests for
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3 continuous variables. There must be no significant differences between the two study
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5 groups at baseline (t1). The effects of predictors (like gender, culture and social
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7 characteristics) on the smoking behaviour after six months (t2) will be calculated by
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9 logistic regression analysis, a state-of-the-art technique for the evaluation of the
10
11 effectiveness of prevention programmes [22, 25, 26] in longitudinal studies. The
12
13 significance level is 5% for t-tests (double-sided) and 95% for confidence intervals
14
15 (double-sided). The statistical analysis will be performed using the newest version of
16
17 SPSS Statistics for Mac by IBM.
18
19

Legal approval

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24 In accordance with Good Epidemiologic Practice (GEP) guidelines [24], the study
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26 protocol was submitted for approval by the responsible ethics committee, which
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28 decided that the study does not need ethical approval (ethics committee of Goethe
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30 University, Frankfurt-Main, Germany). All legal and data protection issues were
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32 discussed with the responsible authority, the Ministry of Education and Cultural
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34 Affairs in Germany, which approved the proposed data collection within the
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36 participating schools. In addition, each school individually discussed and approved
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38 the study at a school conference. It was explained to each student that participation
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40 is voluntarily, and informed written consent was obtained from the parents of the
41
42 study participants.
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Discussion

Strengths and limitations

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3 No evaluation of a medical student-delivered school-based tobacco prevention
4 programme is available to date. It is imperative to sensitize prospective physicians to
5 tobacco prevention [13]. An additional aim of this study is to evaluate whether a
6
7 medical student-delivered smoking prevention program has preventive effects on the
8 smoking behaviour of secondary school pupils in Germany. The data from this study
9
10 will provide a sound basis for optimizing the Education Against Tobacco curriculum to
11 make it optimally effective for different target groups. A promising factor of the EAT
12 programme is that it uses a combined social influence and social competence
13 approach, which was been shown to be effective in the recently published Cochrane
14 Analysis [14].
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26 Our study has a quasi-experimental design. The main problem of this kind of study is
27 selection bias due to the lack of randomization. To minimize this problem, we will
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29 match the intervention classes with ~~parallel~~-control classes (same grade and school),
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31 which corresponds to the matching procedure in field experiments.
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35 As the intervention and control groups attend the same schools, the pupils could
36 exchange what they learn about smoking in the intervention during school breaks.
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38 Therefore cluster effects cannot be excluded entirely.
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42 Also, as our research is not multi-national, it might not be useful for persons of all
43 ethnic and cultural backgrounds.
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48 Because our study relies on self-reports obtained from adolescents via a
49 questionnaire for data collection, there is a risk that the actual prevalence of smoking
50 may be different from the reported prevalence, e.g. due to social desirability bias.
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53 This bias can only be excluded by using expensive methods like testing for cotinine
54 (a metabolite of nicotine) in the saliva, blood or urine of the students. Other
55 alternatives described by Ketala et al. (2004) include the measurement of
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3 thiocyanate in saliva or carbon monoxide in exhaled air [27]. This group reported
4
5 95% agreement between the results of these biochemical tests and the results of
6
7 questionnaires. Conversely, Connor Gorber et al. (2009) found high differences
8
9 between biochemically assessed and self-reported smoking status in pregnant
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11 women and patients with tobacco-related diseases [28]. In our study, there might be
12
13 social desirability bias in both study groups, which might make the intervention look
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15 less effective than it actually is:
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19 The first measurement at baseline occurs while the intervention group is anticipating
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21 the intervention. Therefore, more intervention group students might feel compelled to
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23 behave in a socially desirable way and falsely declare that they are non-smokers. In
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25 contrast, the control group students know that they will not see the medical students
26
27 again anytime soon, so they might be inclined to answer more honestly to the items
28
29 on the questionnaire. At the second measurement time point, the situation is
30
31 reversed: Because the intervention group students know that the medical students
32
33 will not come back, they might feel less social desirability pressure and be more likely
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35 to admit that they are smokers. In contrast, the control group students will be
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37 awaiting the next intervention in the coming weeks, so they might reply to the
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39 questionnaires in a more socially desired way (declaring that they are non-smokers
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41 even if they smoke).
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47 Consequently, the study could be compromised by social desirability bias at both
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49 time points, which could make the intervention look less effective.
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53 In order to measure the long-term effects of school-based programmes, follow-up
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55 data is usually collected six months and one year after an intervention. However, we
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57 will only be able to collect data six months post-intervention because the schools
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3 insisted on us providing an intervention for the control group in the same school year.
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5 Thus, we will not be able to determine which effects the intervention might have at
6
7 one year follow-up.
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10 **Conclusion**

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

33
34 TJB contributed to the design and conduct of the study, drafted the manuscript, and
35
36 will perform the statistical analysis. WS supports the coordination of the study. SS-B
37
38 contributed to the design of the study, participated in the writing process, and
39
40 proofread the manuscript. DAG contributed to the design of the study and proofread
41
42 the manuscript. All authors read and approved the final manuscript. This study is part
43
44 of a thesis project (TJB).
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50 **Competing interests:**

51
52 The authors declare that they have no competing interests.
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54

55 **Funding:**

56
57 Each participating school pays a small fee for the copies of the questionnaire that are
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being distributed to every participating student. There are no other funding sources available.

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between self-reported and cotinine-assessed smoking status. *Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco* 2009, **11**(1):12-24.

For peer review only

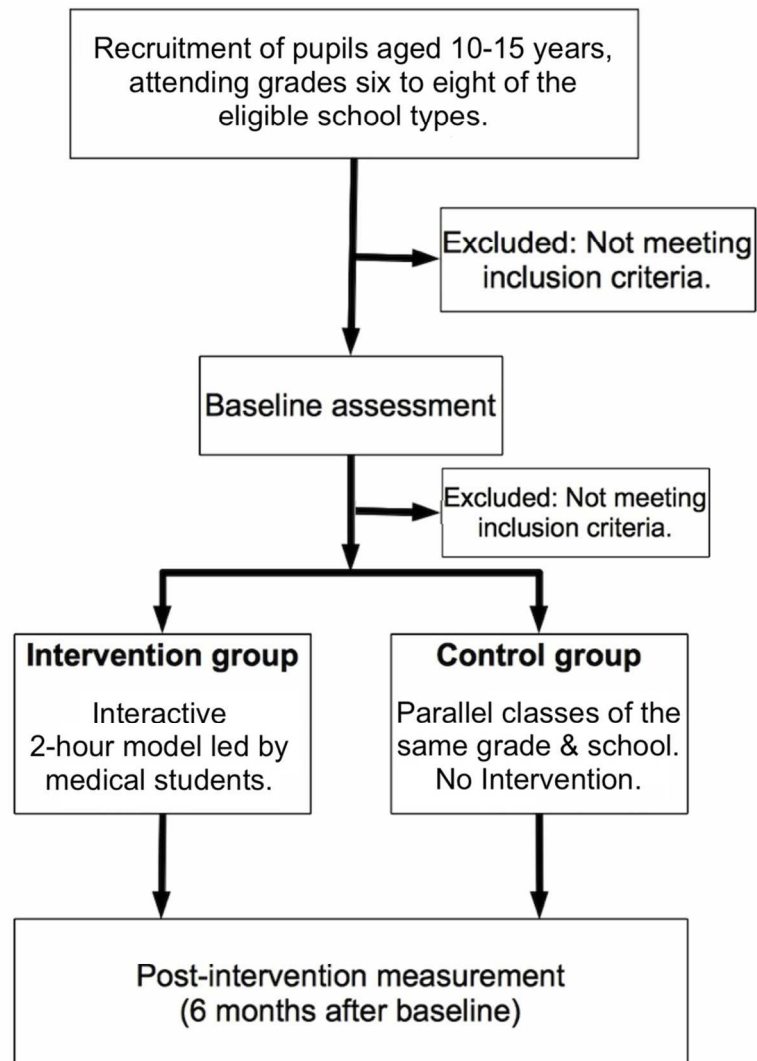


Figure 1
Study design.

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) <i>Case-control study</i> —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) <i>Case-control study</i> —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 <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed checked (e) Describe any sensitivity analyses checked

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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 checked (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*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure checked <i>Cross-sectional study</i> —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
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*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.