



**Effects of a School-Based Prevention Program on Smoking:
Six-Month Follow-up of the 'Eigenständig werden' Cluster
Randomized Trial**

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3 Effects of a School-Based Prevention Program on Smoking: Six-Month Follow-up of the
4 'Eigenständig werden' Cluster Randomized Trial
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ABSTRACT

Objectives: To test the effects of a school-based prevention program on students' smoking related behavior, attitudes and knowledge six months after program implementation has ended.

Design: Two-arm prospective cluster randomized controlled trial with a follow-up survey six months after end of program implementation.

Setting: Forty-five public secondary schools from four federal states in Germany (Bremen, Hesse, North Rhine-Westphalia, Schleswig-Holstein).

Participants: A total of 3,444 students from 172 classes at baseline with a mean age of 10.37 years (SD=0.59) and 47.9% girls. Analysis sample with follow-up up data merged to baseline data comprises 2,513 data sets (73.0%).

Intervention: "Eigenständig werden 5+6", a school-based prevention program for grade five and six to enhance substance specific and general life skills, consisting of 14 units (à 90 minutes) and two workshops (4 resp. 6 hours) being taught over a time period of two years by trained teachers.

Outcome measures: Lifetime and current smoking, incidence of smoking in baseline never smokers, smoking related knowledge, attitudes, perceived norms of smoking, self-efficacy to refuse cigarette offers were assessed in students.

Results: Six months after end of program implementation, students of intervention classes showed significantly lower rates for lifetime smoking (adjusted odds ratio [OR]=0.63; 95% confidence interval [CI]=[0.41; 0.96]; p=0.026) and incidence of smoking (adjusted OR=0.66; 95% CI=[0.43; 1.00]; p=0.047), a higher increase of smoking related knowledge (adjusted β =9.38; 95% CI=[6.73; 12.04]; p<0.001) and a greater change in attitudes towards a more critical perception of risks and disadvantages of smoking (adjusted β =0.10; 95% CI=[0.03; 0.16]; p=0.002). No group differences were found for current smoking, perceived norms of smoking and self-efficacy to refuse cigarette offers.

Conclusions: Participation in the school-based prevention program "Eigenständig werden 5+6" may have small effects on smoking behavior and attitudes and a moderate effect on smoking related knowledge.

Trial registration: Current Controlled Trials ISRCTN99442407

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ARTICLE SUMMARY

Article focus

- School-based prevention programs show inconsistent results concerning efficacy and most of evaluation studies were conducted in the US.
- This study investigates the effects of a prevention program implemented in grade 5 and 6 in German schools on different outcomes six months after end of program using rigorous evaluation methodology.

Key messages

- Program participation seems to reduce prevalence and incidence of lifetime smoking, to increase smoking related knowledge, and to influence attitudes towards a more critical perception of smoking.

Strengths and limitations of this study

- Findings were retrieved from a cluster randomized controlled trial with a well-powered sample and under usage of sophisticated statistical methods controlling for confounders and taking clustering of data into account.
- Drop out, reliance on self-reports and lack of control for treatment integrity may be limiting factors to this study.

BACKGROUND

Smoking remains to be the single greatest preventable cause of mortality worldwide, being a major risk factor for a number of life-threatening diseases, including various cancers, cardiovascular diseases and lung diseases.¹ Though reductions in smoking rates in adolescents have been documented for many Western countries including Germany² over the last decade, smoking prevention is still a main issue for public health.

School programs are often one of the first approaches mentioned in efforts to denormalize tobacco use and to raise awareness of tobacco's hazardous nature. Prominent approaches to prevent smoking in students are the development and improvement of general life skills, as well as the fostering of skills for resisting social influence and substance-specific skills in adolescence. General life skills are considered to empower adolescents in challenging situations and to help them to master life as competent as possible.³ By enhancing these skills, it is assumed to prevent substance use and abuse, since substance use is considered as a dysfunctional strategy to cope with every day challenges and developmental tasks in adolescence. In line with the social influence approach,⁴ smoking is conceptualized as a result of influences emerging from the adolescent's environment like peers, family, or media by normative processes and/or overt cigarette offers. Therefore, correction of inaccurate norms is one important component of these programs to adjust the often overestimated prevalence of smoking in adolescence towards more conservative and realistic norms.⁵ Skill training following these approaches is considered to 'inoculate' students against influences encouraging them to smoke, to help them resist temptations from peers to smoke and to correct normative expectations towards smoking.

For more than 40 years prevention programs have been implemented and evaluated within the school setting. However, empirical evidence of the efficacy of these approaches is not yet uniquely convincing.⁶⁻¹¹ A recent Cochrane review on the effects of school-based smoking prevention trials¹² selected randomized controlled trials where students, classes, schools, or school districts were randomized to intervention arm(s) versus a control group, and followed-up for at least six months. One hundred and thirty-four studies involving 428,293 participants met the inclusion criteria of the review which revealed an overall significant intervention effect on the onset of smoking at longest follow-up, while there was no overall effect at follow-ups at one year or less. When analyzing intervention effects not only on smoking behavior, but also on further outcomes addressed directly or indirectly by school-based interventions like attitudes towards smoking, resistance skills or smoking related knowledge, findings might be condensed into a more or less consistent pattern with medium effects being found for knowledge and, if any, small effects for attitudes, skills and use.¹³⁻¹⁵

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3 Among altogether 37 trials on smoking prevention strategies from the time period 2001 to
4 2006 which were included in a Health Technology Assessment, only one study originated
5 from Germany.¹⁶ The Cochrane Review¹² which covers publications until 2012 included
6 another five studies from Germany, three of them were trials being published until 2000, and
7 two trials being published after 2006 (one of these was a multi-center study with one out of
8 seven centers being located in Germany). Most of these studies had some methodological
9 shortcomings like not adjusting for clustering of data which results from the specific
10 characteristics of the setting with delivery of the intervention to complete classes, and
11 schools or classes instead of individuals being the unit of randomization. Therefore, a lack of
12 rigorous evaluation trials on smoking prevention programs can be inferred especially for
13 Germany.
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21 The present study aims to contribute to overcome shortcomings in evidence for efficacy of
22 school-based smoking prevention by presenting results of cluster randomized trial from
23 Germany. We report findings on 6-month follow-up effects of a school-based curriculum
24 named “Eigenständig werden 5+6” (“Becoming independent 5+6”) for students in grade five
25 and six. The overall aim of “Eigenständig werden 5+6” is the prevention of substance use
26 and abuse by increasing substance specific skills and general life skills of students. Findings
27 presented herein refer to effects of program participation on smoking related knowledge,
28 attitudes towards smoking, perceived norms of smoking, self-efficacy to resist cigarette offers
29 and actual smoking behavior six months after end of program implementation.
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37 **METHODS**

38 **Intervention**

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40 “Eigenständig werden 5+6” is a school-based prevention program for students in grade five
41 and six which takes quality criteria of effective prevention programs into account.^{7;8;17;18}

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43 Based on the life skills approach and on the social influence model, “Eigenständig werden
44 5+6” aims primarily at the prevention of substance use (i.e. tobacco smoking and drinking
45 alcohol) by increasing general life skills as well as substance specific skills (i.e. coping with
46 emotions, stress, problems, pressures to smoke and drink alcohol, increase of refusal skills
47 and decrease of susceptibility to pro-smoking and pro-alcohol social influences).
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52 The program delivers the contents (life skills, students’ ability to work in a group, substance
53 specific skills) in 14 units (most of them lasting 90 minutes) and in two workshops (four to six
54 class hours) that are evenly distributed over the grades five and six. Workshops include
55 several activities about substance use such as smoking cigarettes and alcohol misuse. All
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3 components are realized by trained teachers within daily school-routine. Further details on
4 the program have been described elsewhere.¹⁹
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7 8 **Design**

9 A five-wave cluster randomized-controlled trial with two arms (intervention and control
10 condition) is being conducted in four German federal states (Bremen, Hesse, North Rhine-
11 Westphalia and Schleswig-Holstein) to evaluate effects of “Eigenständig werden 5+6”. The
12 randomization occurred at school level to avoid information exchange between conditions in
13 the school. For randomization, schools were stratified according to the following criteria: (1)
14 study region, (2) type of school, (3) number of fifth grade classes per school. According to
15 these strata, schools were randomly assigned to the two arms of the study with a 50 per cent
16 chance of being allocated to either group by using coin toss method. Intervention group took
17 part in “Eigenständig werden 5+6” and is compared to control group receiving education as
18 usual. Assessments took place prior to the intervention in October/November 2010, post-
19 tests were realized in June/July 2011 and June/July 2012, a 6-month follow-up was being
20 conducted in December 2012 and a 15-month follow-up will take place in September/October
21 2013. For further details, see Hansen et al.¹⁹
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29 30 **Study Sample**

31 Complete lists of all secondary schools of selected regions were obtained from the Ministries
32 of Education of each federal state. An overall of 450 secondary schools in the study regions
33 were invited to participate in the study, of which 323 (71.5%) did neither express approval or
34 disapproval (Figure 1). The decision to participate in the study was expressed by 48 schools
35 (11%) with 191 classes and 4,772 students. Of these 48 schools agreeing to participate, 26
36 schools with 97 classes and 2,437 students were allocated to intervention group whereas 22
37 schools with 94 classes and 2,335 students were assigned to control condition. After
38 randomization, three schools of intervention group withdrew their consent as well as four
39 teachers of intervention classes refused to take part.
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47 Consequently, baseline data comprises 45 schools, 172 classes and 3,444 students with a
48 mean age of 10.37 years (SD=0.59), 47.9% girls, with 1,685 students in 81 classes in
49 intervention and 1,759 students in 91 classes in control condition. In respect to different
50 outcome and covariate characteristics, intervention and control students were extensively
51 comparable with the exception of a higher proportion of students of Gymnasiums in control
52 condition (for sample size determination and detailed baseline sample description see¹⁹).
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55 Data presented herein refer to baseline (October 2010) and 6-month follow-up survey
56 (December 2012). It was possible to merge follow-up data of 1,255 students in intervention
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3 arm and 1,438 students in control arm (total N=2,693, 78.2% of N=3,444) to baseline data.
4 For analysis, data sets with inconsistencies concerning age, gender, and smoking status
5 were excluded (N=180). The final analysis sample consists of 2,513 data sets (intervention
6 group: N=1,179, control group: N=1,334).
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12 13 **Measures**

14 Data was collected through self-completed anonymous questionnaires by teachers and
15 students. Development of questionnaire and a complete list of variables and constructs
16 assessed in the trial have been documented.¹⁹ Analysis presented herein, rely on the
17 following outcome measures: *Lifetime smoking* experience was assessed by asking how
18 many cigarettes have ever been smoked in life. Nine answering categories ('none', 'only a
19 few puffs', '1 cigarette', '2 cigarettes', '3-4 cigarettes', '5-9 cigarettes', '10-19 cigarettes', '20-
20 100 cigarettes', '>100 cigarettes') were provided. Students having smoked at least a few
21 puffs were considered as ever smokers. *Smoking incidence* at follow-up among baseline
22 never smokers was determined by combining answers to lifetime smoking at baseline and
23 follow-up: those who had never smoked at baseline, and indicated any smoking by the
24 follow-up survey, even just a few puffs, were considered as having initiated smoking during
25 the observation period. *Current smoking* frequency was measured by asking how many
26 cigarettes are currently smoked. Respondents could answer 'I don't smoke,' 'less than once
27 a month', 'at least once a month, but not weekly', 'at least once a week, but not daily,' or
28 'daily'. Responses were dichotomized into students not smoking and students indicating any
29 kind of current smoking.
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41 To assess *attitudes towards smoking and risk perception*, respondents should rate eleven
42 statements (e.g. 'Non-smokers are fitter', 'Non-smokers are cooler', 'If I smoke during the
43 next month, I will get in trouble with my friends'). Answer categories comprise 0='not true',
44 1='somewhat true', 2='rather true', and 3= 'totally true', i.e. higher values represent a more
45 negative attitude towards smoking and more sensitive perception of risk. Cronbach's Alpha
46 of this scale was 0.80. Change in attitude from baseline to follow-up was determined by
47 subtracting baseline value from follow-up value for each respondent. *Smoking related*
48 *knowledge* was tested through seven statements (e.g. 'Cigarettes contain arsenic which is
49 also found in rat poison.') to which respondents could either agree by answering 'true' or
50 disagree by stating 'wrong' or state 'I don't know'. As indicator of knowledge, percentage of
51 correct classification of statements was determined. Increase in knowledge from baseline to
52 follow-up was determined by subtracting baseline value from follow-up value for each
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3 respondent. *Normative expectations* were measured on an 11-point scale ranging from
4 0='nobody' to 10='everybody' on which students had to estimate how many a) 'Adults in
5 Germany' and b) 'Adolescents at their age' in Germany smoke. *Self-efficacy* to refuse
6 cigarette offers were assessed by asking 'To what extent do you dare to refuse cigarettes,
7 even if your friends laugh at you or suspend you on that account?' with answer categories
8 ranging from 0='not at all' to 3='totally'. Normative expectations and self-efficacy were
9 analyzed on single item level.
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15 *Covariate measures* were derived from studies that focused on risk factors of adolescent
16 tobacco use, to control for confounding variables that would be theoretically related to the
17 smoking measures.²⁰⁻²² Sociodemographics include age, gender, type of school (Gymnasium
18 vs. other type of school), migration background (mother and/or father were born outside
19 Germany) and socio-economic status (SES, Family Affluence Scale²³). As personal
20 characteristics, rebelliousness and sensation-seeking were assessed with two items in each
21 case.^{24,25} Parent, sibling and peer smoking were assessed as factors from social
22 environment (no vs. any parent/sibling/peer smoking). Finally, students were asked whether
23 they had participated in a comprehensive prevention program in elementary school with
24 examples of most broadly disseminated programs given.
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32 **Procedure**

33 In schools having agreed to participate, teachers of the respective 5th grade collected the
34 parental informed consent. Students with refusal were excluded from all assessments. Data
35 assessment was conducted in the class room and lasted 45 minutes. Research staff was
36 responsible for the distribution, help in completion and collection of the questionnaire. To
37 permit a linking of individual baseline and follow-up data while assuring anonymity, students
38 generated a seven digit individual code. This procedure has been tested and used in several
39 studies and therefore been inspected and approved by Ethics Committee, data protection
40 and Ministries of Education repeatedly.²⁶ Teachers were not involved in data assessment. At
41 the end of the assessment, all questionnaires were placed in an envelope which was sealed
42 in front of the class. Therefore, every student was assured that neither teachers nor parents
43 were able to see the completed questionnaire.
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51 Ethical approval for the trial was gained from the Ethics Committee of Medical Faculty of the
52 University of Kiel. Additional approvals (e.g., from ministries of education, and parents) were
53 sought as required.
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58 **Analyses**

Predictors of attrition were examined by logistic regressions, χ^2 - and t-tests. To test for selective attrition, interaction effects for group condition and dependent variable were tested. Descriptive statistics (percentages, means, standard deviations) are crude values. To analyze effects of the intervention on smoking behavior as well as on attitudes and knowledge, multilevel mixed effect regression models using Stata *mixed* and *meqrlogit* command were conducted, adjusting for covariates. In case of dichotomous outcomes, effect sizes (Cohen's d) were determined by using the converting formula proposed by Borenstein et al.²⁷ Effect sizes for metric outcomes were calculated as proposed by Feingold.²⁸ All data analyses were conducted with Stata V.13.²⁹

RESULTS

Attrition analysis

Among the 3,444 students assessed at baseline, there was no data available in the analysis sample for 931 students (27.0%). Drop-out was higher in intervention group (N=506, 30.0%) compared to control group (N=425, 24.2%; $\chi^2(1)=15.02$, $p<0.001$). Overall, significantly higher attrition was also found for male students (31.2%; $p<0.001$), students attending other schools than *Gymnasium* (32.1%; $p<0.001$), students with a migration background (36.5%; $p<0.001$), students indicating current smoking (45.7%; $p=0.004$) or current use of alcohol (39.8%; $p<0.001$) at baseline. Furthermore, students dropping out of the study were older ($M_{\text{attrition}}=10.5$ vs. $M_{\text{retention}}=10.3$ years of age at baseline; $p<0.001$) and had a lower SES ($M_{\text{attrition}}=17.1$ vs. $M_{\text{retention}}=17.9$; $p<0.001$) than students in the retention sample. Besides these overall effects, no hints for selective attrition were found, i.e. the associations between variables listed above and attrition did not differ systematically between intervention and control group.

Effects on smoking behavior

Students in intervention and control group did not differ in rates for lifetime and current smoking at baseline. At follow-up, 16.0% of intervention students indicated that they had ever smoked in their lives compared to 20.2% in the control students (Figure 2). This difference was statistically significant also after controlling for confounding factors (adjusted Odds Ratio [OR]=0.63; 95% confidence interval [CI]=[0.41; 0.96]; $p=0.026$).

While about 1% of intervention and control students reported current smoking at baseline, these rates increased to more than 5% at follow-up both in intervention and control group. Therefore, no group differences could be found in frequency of current smoking.

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3 At baseline, 95.6% of the sample were never-smokers (N=2,403; IG: 96.4%, CG: 94.9%).
4 Among these baseline never-smokers, 15.5% initiated smoking during the observation
5 period. Incidence rate was significantly lower in intervention students, among whom 13.7%
6 reported first use of cigarettes between baseline and follow-up, compared to control group
7 with an incidence rate of 17.1% (adjusted OR=0.66, 95% CI=[0.43; 1.00], p=0.047).
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14 **Effects on smoking related knowledge and attitudes**

15 Students of both groups showed about the same level of smoking related knowledge at
16 baseline with correct answering rates of about 30% (Table 1). At follow-up, students in both
17 groups scored better in the knowledge test: intervention students had a mean percentage of
18 correct answers of 46.75, while intervention students rated on average 37.74% of the
19 statements correctly. The increase in knowledge was significantly higher in intervention
20 students (adjusted $\beta=9.38$; 95% CI=[6.73; 12.04]; $p<0.001$).
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30 A comparable pattern was found for attitudes towards smoking: At baseline, both groups did
31 not differ in their attitudes and showed a rather critical perception of smoking with a mean
32 score of 2.04 on the scale ranging from 0 to 3 (Table 1). At follow-up, students rated smoking
33 even more negatively with a mean score of 2.24 in intervention and 2.16 in control group.
34 Compared to control group, this change in attitudes was more pronounced in intervention
35 group (adjusted $\beta=0.10$; 95% CI=[0.03; 0.16]; $p=0.002$).
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40 Normative expectations were hardly influenced by the intervention: While intervention
41 students estimated smoking prevalence in adults marginally lower at follow-up compared to
42 their estimation at baseline, a small increase in this estimate could be observed in control
43 students (Table 1). For peer smoking, both groups showed a small increase in perceived
44 frequency of smoking. None of these changes turned out to be statistically significant after
45 covariates and baseline estimates were controlled for.
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52 Already at baseline, students in both groups considered themselves rather capable to refuse
53 cigarette offers (Table 1). During observation period, self-efficacy even grew with a slightly
54 higher – but statistically insignificant – increase in intervention students compared to control
55 students.
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Table 1.
 Descriptive statistics and multilevel mixed effects linear regressions for smoking related knowledge, attitudes, perceived norms and self-efficacy to refuse cigarette offers

	Baseline		Follow-up		Change		Difference in change		
	Beginning of grade 5		Mid of grade 7		Intervention	Control	adj. β^1	95% CI	p
	Intervention	Control	Intervention	Control					
	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)			
Knowledge ²	30.34 (19.47)	30.11 (19.14)	46.75 (21.59)	37.74 (20.45)	16.53 (26.46)	7.53 (24.13)	9.38	6.73; 12.04	<0.001
Attitudes/risk perception ³	2.04 (0.51)	2.04 (0.51)	2.24 (0.51)	2.16 (0.54)	0.20 (0.61)	0.12 (0.61)	0.10	0.03; 0.16	0.002
Norms adult smoking ⁴	6.08 (1.62)	5.97 (1.59)	6.04 (1.62)	6.09 (1.55)	-0.03 (2.09)	0.12 (1.95)	-0.08	-0.24; 0.07	0.265
Norms peer smoking ⁴	3.08 (2.64)	2.93 (2.56)	4.24 (2.28)	4.02 (2.18)	1.16 (3.10)	1.10 (2.93)	0.15	-0.13; 0.43	0.283
Self-efficacy to refuse cigarettes ⁵	2.38 (1.04)	2.36 (1.03)	2.53 (0.80)	2.49 (0.85)	0.15 (1.20)	0.11 (1.22)	0.07	-0.03; 0.17	0.140

M = Mean, SD = Standard deviation, CI = Confidence interval

¹ Adjusted for age, gender, type of school, socio-economic status, immigration background, peer / parent / sibling smoking, sensation seeking, rebelliousness, earlier participation in prevention program, baseline value of the respective variable

² Mean percentage of correct answers in a 7-item quiz

³ Range 0 to 3, higher values representing more negative attitude

⁴ Range 0 = nobody smokes to 10 = everybody smokes

⁵ Range 0-3, higher values representing higher self-efficacy

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3 Effect sizes for significant program effects were small to medium with $d=0.26$ (lifetime
4 smoking), $d=0.23$ (incidence of smoking), $d=0.45$ (smoking related knowledge), and $d=0.15$
5 (attitudes/risk perception).
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10 DISCUSSION

11 The current study aimed to investigate effects of a school-based prevention program on
12 smoking related knowledge, attitudes and behavior six months after end of program
13 implementation. Using a cluster randomized controlled design, findings revealed that
14 program participation seems to reduce prevalence and incidence of lifetime smoking, to
15 increase smoking related knowledge, and to influence attitudes and perceived risks of
16 smoking towards a more critical perception. Program effects on prevalence of current
17 smoking, normative expectations or refusal skills could not be determined. Using Cohen's
18 classification of effect sizes,³⁰ effect size was small for smoking behavior and attitudes, while
19 there was a medium effect on smoking related knowledge.
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27 The pattern found for effects on smoking behavior with significant small effects on smoking
28 incidence ($d=0.23$) and lifetime smoking ($d=0.26$), and no effect on current smoking can be
29 aligned quite well with results presented in former meta-analyses: The pooled odds ratio of
30 0.88 for smoking onset at longest follow-up revealed by the overall analysis of Thomas et
31 al.¹² corresponds to an effect size of $d=0.07$, while their subgroup analyses for different
32 intervention approaches provided even moderate effect sizes (odds ratios between 0.49 and
33 0.52 corresponding to d 's between 0.36 and 0.39). Earlier meta-analyses on school-based
34 drug prevention programs,¹³ psychosocial smoking prevention programs¹⁴ or studies on
35 Project DARE (Drug Abuse Resistance Education),¹⁵ the most widely used school-based
36 drug prevention program in the United States and focusing on teaching skills to recognize
37 and resist social pressure, also determined small program effects on substance use with d 's
38 ranging between 0.08 and 0.18. Finding no effect on current smoking might also be
39 explained to some extent by the young age of the sample with only very few students
40 smoking already on a regular basis.
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50 Participation in "Eigenständig werden 5+6" significantly increased smoking related
51 knowledge with an effect size of $d=0.45$ – the highest effect found in our analyses. This
52 medium effect is in line with effect sizes ranging from 0.36 to 0.42 determined in meta-
53 analyses referred to above.¹³⁻¹⁵ Attitudes were influenced also significantly by the
54 intervention, the small effect ($d=0.15$) compares well with small effects in a range from 0.11
55 to 0.26 having been reported.¹³⁻¹⁵
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4 We were not able to show an effect of the intervention in correcting perceived norms of
5 smoking or self-efficacy to refuse offered cigarettes. Students of both intervention and control
6 group consider themselves to be rather highly self-efficacious to resist to cigarette offers
7 already at the outset of the study and this rating even increases in both groups at follow-up,
8 i.e. a ceiling effect might decrease discriminative power of the group comparisons. As far as
9 perceived norms of smoking are concerned, a possible explanation of the null-effect is the
10 fact that only a minor part of the intervention (one subtask among nine tasks of the smoking
11 workshop at the end of grade 5) deals with the topic of norms. Most tasks in the workshop
12 address facts about and visualization of short- and long-term consequences of smoking,
13 others aim to scrutinize strategies of tobacco industry or to foster resistance skills.
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21 Some limitations of the current study have to be considered: There has been some drop-out
22 from the study from baseline to follow-up; the analysis sample (N=2,513) amounted to 73.0%
23 of the baseline sample (N=3,444). Nevertheless, we did not find any hints for selective
24 attrition which could restrict the validity of findings. The curriculum "Eigenständig werden
25 5+6" comprises of 14 lessons à on average 90 minutes and two workshops with 4 to 6 hours
26 of duration which are implemented by teachers in addition to usual education, i.e. the
27 program is quite time-consuming, it requires some dedication by teachers and it seems
28 unreasonable to assume that the intervention is delivered to all classes exactly in the way
29 and to the extent foreseen by the manual. Analyses in this report were not controlled for
30 treatment integrity,^{31;32} i.e. classes with low treatment fidelity and having been exposed only
31 to parts of the intervention contribute to the same extent to the results of the intervention
32 group as classes with complete program implementation and results can be considered as
33 rather conservative. Another limitation is the reliance on self-reports in the assessment of
34 outcomes. Especially for outcomes assessing smoking behavior, but also for attitudes
35 towards smoking, answers might be biased by social desirability. These influences might
36 occur more likely in the intervention group since students might be primed by the intervention
37 that smoking is an "unwanted" behavior. Nevertheless, since purchase of cigarettes and
38 smoking in public is forbidden by law for minors in Germany, also the students in the control
39 condition are not free of a social desirability bias. For other outcomes like the assessment of
40 refusal skills, validity of self-report data might be limited by restricted accessibility, i.e.
41 whether adolescents are really able to judge their own competence to resist cigarette offers.
42 Finally, the study was run in four federal states of Germany, i.e. generalizability might be
43 limited due to these regional constraints.
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3 On the other hand, some strengths of the current studies should be born in mind: Results
4 were derived from a cluster randomized controlled trial, applying sophisticated statistical
5 methods, comprising a range of several outcomes and following students up for six months
6 after the end of intervention. Therefore, we implemented rather rigorous evaluation methods,
7 which are in line with recommendations like those of the Society for Prevention Research.³³
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11 Perspectives and open questions for future research might be the following: In the current
12 trial, a further follow-up at 15 months after end of intervention is being conducted to explore
13 stability of effects in the longer term. Furthermore, exploring effects on other outcomes than
14 smoking, e.g. alcohol use or life skills, is owing for the current study. Finally, besides stating
15 whether an intervention is effective or not, mechanisms by which shown effects can be
16 explained theoretically and empirically are to be explored. These mediation analyses may
17 contribute to investigate causal models for preventive intervention, e.g. to explore whether
18 knowledge or change in attitude are necessary preconditions for behavior change.¹³
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Figure legends

Figure 1. Participation flowchart

Figure 2. Percentage of lifetime smoking, current smoking at baseline and 6-month follow-up, percentage of smoking incidence at 6-month follow-up among baseline never-smokers, and multilevel mixed effects logistic regressions; OR = odds ratio, CI = confidence interval; logistic regressions were adjusted for age, gender, type of school, socio-economic status, immigration background, peer / parent / sibling smoking, sensation seeking, rebelliousness, earlier participation in prevention program

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Competing interests

None.

Ethics approval

Ethics approval was provided by the Ethics Committee of the Medical Faculty of the University of Kiel (Ref.: D 419/10).

Contributors

BI performed the statistical analysis and interpretation of data and drafted the manuscript. JH contributed to acquisition of data and participated in drafting the manuscript. KM contributed to acquisition and management of data. RH as principle investigator is responsible for study concept, design and supervision and helped in drafting the manuscript.

All authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors conducted a critical revision of the article and granted final approval of the article for important intellectual content.

Data sharing statement

No additional data available.

REFERENCES

- (1) Lim SS, Vos T, Flaxman AD, Danaei G, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2013; 380(9859):2224-2260.
- (2) Bundeszentrale für gesundheitliche Aufklärung. Der Tabakkonsum Jugendlicher und junger Erwachsener in Deutschland 2012. Ergebnisse einer aktuellen Repräsentativbefragung und Trends. Köln: Bundeszentrale für gesundheitliche Aufklärung; 2013.
- (3) World Health Organisation. Life skills education in schools, parts 1 and 2. Geneva: WHO, Division of Mental Health; 1994.
- (4) Evans RI. Smoking in children: developing a social psychological strategy of deterrence. *Prev Med* 1976; 51:122-127.
- (5) Donaldson SI, Graham JW, Hansen WB. Testing the generalizability of intervening mechanism theories: understanding the effects of adolescent drug use prevention interventions. *J Behav Med* 1994; 17(2):195-216.
- (6) Flay BR. The promise of long-term effectiveness of school-based smoking prevention programs: a critical review of reviews. *Tob Induc Dis* 2009; 5(1):7.
- (7) Cuijpers P. Effective ingredients of school-based drug prevention programs. A systematic review. *Addict Behav* 2002; 27(6):1009-1023.
- (8) Gottfredson DC, Wilson DB. Characteristics of effective school-based substance abuse prevention. *Prev Sci* 2003; 4(1):27-38.
- (9) Flay BR. School-based smoking prevention programs with the promise of long-term effects. *Tob Induc Dis* 2009; 5(1):6.
- (10) Skara S, Sussman S. A review of 25 long-term adolescent tobacco and other drug use prevention program evaluations. *Prev Med* 2003; 37(5):451-474.
- (11) Wiehe SE, Garrison MM, Christakis DA, Ebel BE, Rivara FP. A systematic review of school-based smoking prevention trials with long-term follow-up. *J Adolesc Health* 2005; 36(3):162-169.
- (12) Thomas RE, McLellan J, Perera R. School-based programmes for preventing smoking. *Cochrane Database Syst Rev* 2013; 4:CD001293.
- (13) Tobler NS, Stratton HH. Effectiveness of school-based drug prevention programs: a meta-analysis of the research. *J Prim Prev* 1997; 18(1):71-128.
- (14) Hwang MS, Yeagley KL, Petosa R. A meta-analysis of adolescent psychosocial smoking prevention programs published between 1978 and 1997 in the United States. *Health Educ Behav* 2004; 31(6):702-719.

- 1
2
3 (15) Ennett ST, Tobler NS, Ringwalt CL, Flewelling RL. How effective is drug abuse
4 resistance education? A meta-analysis of Project DARE outcome evaluations. *Am J*
5 *Public Health* 1994; 84(9):1394-1401.
6
7 (16) Müller-Riemenschneider F, Rasch A, Bockelbrink A, Vauth C, Willich SN, Greiner W.
8 Effectiveness and cost-effectiveness of behavioural strategies in the prevention of
9 cigarette smoking. *GMS Health Technol Assess* 2008; 4:Doc10.
10
11 (17) Cuijpers P. Three decades of drug prevention research. *Drug Educ Prev Polic* 2003;
12 10(1):7-20.
13
14 (18) Hansen WB, Dusenbury L, Bishop D, Derzon JH. Substance abuse prevention
15 program content: systematizing the classification of what programs target for change.
16 *Health Educ Res* 2007; 22(3):351-360.
17
18 (19) Hansen J, Hanewinkel R, Maruska K, Isensee B. The 'Eigenständig werden'
19 prevention trial: a cluster randomised controlled study on a school-based life skills
20 programme to prevent substance use onset. *BMJ Open* 2011; 1(2):e000352.
21
22 (20) Gibbons FX, Gerrard M. Predicting young adults' health risk behavior. *J Pers Soc*
23 *Psychol* 1995; 69(3):505-517.
24
25 (21) Hawkins JD, Catalano RF, Miller JY. Risk and protective factors for alcohol and other
26 drug problems in adolescence and early adulthood: implications for substance abuse
27 prevention. *Psychol Bull* 1992; 112(1):64-105.
28
29 (22) Petraitis J, Flay BR, Miller TQ. Reviewing theories of adolescent substance use:
30 organizing pieces in the puzzle. *Psychol Bull* 1995; 117(1):67-86.
31
32 (23) Currie C, Molcho M, Boyce W, Holstein B, Torsheim T, Richter M. Researching health
33 inequalities in adolescents: the development of the Health Behaviour in School-Aged
34 Children (HBSC) family affluence scale. *Soc Sci Med* 2008; 66(6):1429-1436.
35
36 (24) Stephenson MT, Hoyle RH, Palmgreen P, Slater MD. Brief measures of sensation
37 seeking for screening and large-scale surveys. *Drug Alcohol Depend* 2003;
38 72(3):279-286.
39
40 (25) Burt RD, Dinh KT, Peterson Jr AV, Sarason IG. Predicting adolescent smoking: a
41 prospective study of personality variables. *Prev Med* 2000; 30(2):115-125.
42
43 (26) Galanti MR, Siliquini R, Cuomo L, Melero JC, Panella M, Faggiano F. Testing
44 anonymous link procedures for follow-up of adolescents in a school-based trial: The
45 EU-DAP pilot study. *Prev Med* 2007; 44(2):174-177.
46
47 (27) Borenstein M, Hedges LV, Higgins JPT, Rothstein HR. Introduction to meta-analysis.
48 Chichester: Jon Wiley & Sons; 2009.
49
50 (28) Feingold A. Effect sizes for growth-modeling analysis for controlled clinical trials in the
51 same metric as for classical analysis. *Psychol Methods* 2009; 14(1):43-53.
52
53 (29) StataCorp. Stata Statistical Software: Release 13. College Stations, Texas:
54 StataCorp; 2013.
55
56 (30) Cohen J. Statistical power analyses for behavioral science. Hilldale, New York:
57 Erlbaum; 1988.
58
59
60

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2
3 (31) Bishop DC, Pankratz MM, Hansen WB, Albritton J, Albritton L, Strack J. Measuring
4 Fidelity and Adaptation: Reliability of a Instrument for School-Based Prevention
5 Programs. *Eval Health Prof* 2013.
6
7 (32) Dusenbury L, Brannigan R, Falco M, Hansen WB. A review of research on fidelity of
8 implementation: implications for drug abuse prevention in school settings. *Health*
9 *Educ Res* 2003; 18(2):237-256.
10
11 (33) Flay BR, Biglan A, Boruch RF, Castro FG, Gottfredson D, Kellam S et al. Standards
12 of evidence: criteria for efficacy, effectiveness and dissemination. *Prev Sci* 2005;
13 6(3):151-175.
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BMJ Open
Assessed for eligibility: 450 schools

Denial:
79 schools (17,5%)
No statement:
323 schools (71,5%)

Randomisation: 48 schools (11%)

Allocated to intervention group
26 schools/ 97 classes
2,437 students

Allocated to control group
22 schools/ 94 classes
2,335 students

Withdrawal of consent:
schools:
3 schools, 12 classes, 321 students
teachers:
4 classes, 102 students

Withdrawal of consent:
teachers:
3 classes, 84 students

No parental permission:
231 students
Absent:
98 students

No parental permission:
361 students
Absent:
131 students

Baseline Assessment
23 schools/ 81 classes
1,685 students

Baseline Assessment
22 schools/ 91 classes
1,759 students

Drop-out of 14 classes with 316 students

Drop-out of 7 classes with 150 students

Follow-up Assessment
Available data:
21 schools/ 67 classes/ 1,407 students
Matched to baseline: 1,255 students

Follow-up Assessment
Available data:
21 schools/ 84 classes/ 1,678 students
Matched to baseline: 1,438 students

Excluded due to inconsistent data: 76 students

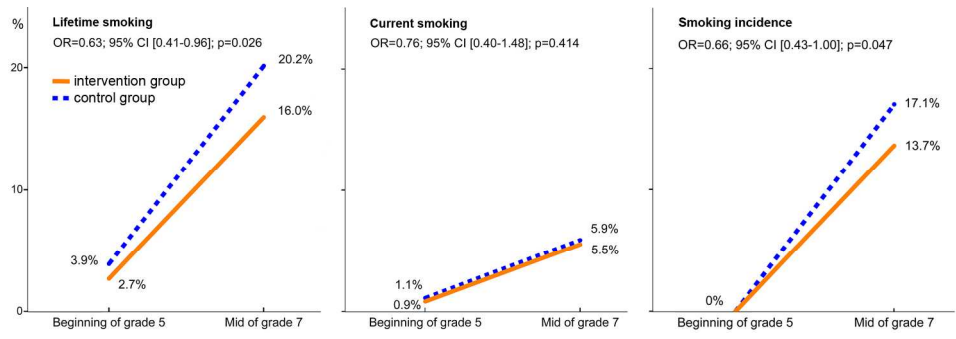
Excluded due to inconsistent data: 104 students

Analysis Sample
1,179 students

Analysis Sample
1,334 students

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202x65mm (300 x 300 DPI)

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Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	p. 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	p. 2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	p. 5
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	p. 5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	p. 6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		p. 6
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	p. 6
	4b	Settings and locations where the data were collected		p. 6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	p. 5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	p. 7

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n.a.
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or <i>k</i>), and an indication of its uncertainty	p. 6
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n.a.
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		p. 6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	p. 6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	p. 6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	p. 6
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	p. 6

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	p. 8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		n.a.
	11b	If relevant, description of the similarity of interventions		n.a.
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	p. 9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		p. 9
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	p. 6 Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	p.6
Recruitment	14a	Dates defining the periods of recruitment and follow-up		p. 6
	14b	Why the trial ended or was stopped		n.a.
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	p. 6
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	p. 9-
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		p. 9-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		p. 9-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		p. 13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	p. 13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		p. 12-
Other information				
Registration	23	Registration number and		p. 2

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	p. 6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p. 15

* Note: page numbers optional depending on journal requirements

For peer review only



**Effects of a School-Based Prevention Program on Smoking
in early Adolescence: Six-Month Follow-up of the
'Eigenständig werden' Cluster Randomized Trial**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2013-004422.R1
Article Type:	Research
Date Submitted by the Author:	10-Dec-2013
Complete List of Authors:	Isensee, Barbara; Institute for Therapy and Health Research, IFT-Nord, Hansen, Julia; Institute for Therapy and Health Research, Maruska, Karin; Institute for Therapy and Health Research, Hanewinkel, Reiner; Institute for Therapy and Health Research,
Primary Subject Heading:	Public health
Secondary Subject Heading:	Addiction, Smoking and tobacco
Keywords:	Substance misuse < PSYCHIATRY, PUBLIC HEALTH, school based prevention, smoking, cluster randomized controlled trial, efficacy

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Manuscripts

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3 Effects of a School-Based Prevention Program on Smoking in early Adolescence: Six-Month
4 Follow-up of the 'Eigenständig werden' Cluster Randomized Trial
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26 Key words: smoking; school-based prevention; cluster randomized controlled trial; efficacy
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30 Word count main text: 4,398
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ABSTRACT

Objectives: To test the effects of a school-based prevention program on students' smoking related behavior, attitudes and knowledge six months after implementation over two school-years has ended.

Design: Two-arm prospective cluster randomized controlled trial with a follow-up survey six months after end of program implementation, i.e. 26 months after baseline.

Setting: Forty-five public secondary schools from four federal states in Germany (Bremen, Hesse, North Rhine-Westphalia, Schleswig-Holstein).

Participants: A total of 3,444 students from 172 classes with a mean age of 10.37 years (SD=0.59) and 47.9% girls at baseline. Analysis sample with follow-up up data merged to baseline data comprises 2,513 data sets (73.0%).

Intervention: "Eigenständig werden 5+6", a school-based prevention program for grade five and six to enhance substance specific and general life skills, consisting of 14 units (à 90 minutes) and two workshops (4-6 hours) being taught over a time period of two school-years by trained teachers.

Outcome measures: Lifetime and current smoking, incidence of smoking in baseline never smokers, smoking related knowledge, attitudes, perceived norms of smoking, self-efficacy to refuse cigarette offers were assessed in students.

Results: Six months after end of program implementation, students of intervention classes showed significantly lower rates for lifetime smoking (adjusted odds ratio [OR]=0.63;95% confidence interval [CI]=[0.41; 0.96];p=0.026) and incidence of smoking (adjusted OR=0.66; 95%CI=[0.43; 1.00];p=0.047), a higher increase of smoking related knowledge (adjusted β =9.38; 95%CI=[6.73; 12.04];p<0.001) and a greater change in attitudes towards a more critical perception of risks and disadvantages of smoking (adjusted β =0.10; 95%CI=[0.03; 0.16];p=0.002). No group differences were found for current smoking, perceived norms of smoking and self-efficacy to refuse cigarette offers.

Conclusions: Participation in the school-based prevention program "Eigenständig werden 5+6" may have small effects on smoking behavior and attitudes and a moderate effect on smoking related knowledge.

Trial registration: Current Controlled Trials ISRCTN99442407

Word count abstract: 298 words

ARTICLE SUMMARY

Article focus

- School-based prevention programs show inconsistent results concerning efficacy and most of evaluation studies were conducted in the US.
- This study investigates the effects of a prevention program implemented in young adolescents in German schools on different outcomes six months after the end of the two school-years lasting program implementation using rigorous evaluation methodology.

Key messages

- Program participation seems to reduce the prevalence and incidence of lifetime smoking, to increase smoking related knowledge, and to influence attitudes towards a more critical perception of smoking.

Strengths and limitations of this study

- Findings were retrieved from a cluster randomized controlled trial with a well-powered sample and under usage of sophisticated statistical methods controlling for confounders and taking clustering of data into account.
- Drop out, reliance on self-reports and lack of control for treatment integrity may be limiting factors to this study.

BACKGROUND

Smoking remains to be the single greatest preventable cause of mortality worldwide, being a major risk factor for a number of life-threatening diseases, including various cancers, cardiovascular diseases and lung diseases.¹ Though reductions in smoking rates in adolescents have been documented for many Western countries including Germany² over the last decade, smoking prevention is still a main issue for public health. Most recent data from Germany reveal smoking rates of about 12% for both female and male adolescents aged 12 to 17 years and 6.6% for young adolescents aged 12 to 15 years.^{2,3}

School programs are often one of the first approaches mentioned in efforts to denormalize tobacco use and to raise awareness of tobacco's hazardous nature. Prominent approaches to prevent smoking in students are the development and improvement of general life skills, as well as the fostering of skills for resisting social influence and substance-specific skills in adolescence. General life skills are considered to empower adolescents in challenging situations and to help them to master life as competent as possible.⁴ By enhancing these skills, it is assumed to prevent substance use and abuse, since substance use is considered as a dysfunctional strategy to cope with every day challenges and developmental tasks in adolescence. In line with the social influence approach,⁵ smoking is conceptualized as a result of influences emerging from the adolescent's environment like peers, family, or media by normative processes and/or overt cigarette offers. Therefore, correction of inaccurate norms is one important component of these programs to adjust the often overestimated prevalence of smoking in adolescence towards more conservative and realistic norms.⁶ Skill training following these approaches is considered to 'inoculate' students against influences encouraging them to smoke, to help them resist temptations from peers to smoke and to correct normative expectations towards smoking.

For more than 40 years prevention programs have been implemented and evaluated within the school setting. However, the empirical evidence of the efficacy of these approaches is not yet uniquely convincing.⁷⁻¹² A recent Cochrane review on the effects of school-based smoking prevention trials¹³ selected randomized controlled trials where students, classes, schools, or school districts were randomized to intervention arm(s) versus a control group, and followed-up for at least six months. One hundred and thirty-four studies involving 428,293 participants met the inclusion criteria of the review which revealed an overall significant intervention effect on the onset of smoking at longest follow-up, while there was no overall effect at follow-ups at one year or less. When analyzing intervention effects not only on smoking behavior, but also on further outcomes addressed directly or indirectly by school-based interventions like attitudes towards smoking, resistance skills or smoking

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3 related knowledge, findings might be condensed into a more or less consistent pattern with
4 medium effects being found for knowledge and, if any, small effects for attitudes, skills and
5 use.¹⁴⁻¹⁶
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9 Among altogether 37 trials on smoking prevention strategies from the time period 2001 to
10 2006 which were included in a Health Technology Assessment, only one study originated
11 from Germany.¹⁷ The Cochrane Review¹³ which covers publications until 2012 included
12 another five studies from Germany, three of them were trials being published until 2000, and
13 two trials being published after 2006 (one of these was a multi-center study with one out of
14 seven centers being located in Germany). Most of these studies had some methodological
15 shortcomings like not adjusting for the clustering of data which results from the specific
16 characteristics of the setting with delivery of the intervention to complete classes, and
17 schools or classes instead of individuals being the unit of randomization. Therefore, a lack of
18 rigorous evaluation trials on smoking prevention programs can be inferred especially for
19 Germany.
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27 The present study aims to contribute to overcome shortcomings in the evidence for the
28 efficacy of school-based smoking prevention by presenting results of a cluster randomized
29 trial from Germany. We report findings on the 6-month follow-up effects of a school-based
30 curriculum named “Eigenständig werden 5+6” (“Becoming independent 5+6”) for students in
31 grade five and six when they are about 10 to 12 years old. The overall aim of “Eigenständig
32 werden 5+6” is the prevention of substance use and abuse by increasing substance specific
33 skills and general life skills of students. Findings presented herein refer to effects of program
34 participation on smoking related knowledge, attitudes towards smoking, perceived norms of
35 smoking, self-efficacy to resist cigarette offers and actual smoking behavior six months after
36 the implementation over two school-years has ended, i.e. on average 26 months after
37 baseline.
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48 **METHODS**

49 **Intervention**

50 “Eigenständig werden 5+6” is a school-based prevention program for students in grade five
51 and six which takes quality criteria of effective prevention programs into account.^{8,9,18,19}
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53 Based on the life skills approach and on the social influence model, “Eigenständig werden
54 5+6” aims primarily at the prevention of substance use (i.e. tobacco smoking and drinking
55 alcohol) by increasing general life skills as well as substance specific skills (i.e. coping with
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3 emotions, stress, problems, pressures to smoke and drink alcohol, increase of refusal skills
4 and decrease of susceptibility to pro-smoking and pro-alcohol social influences).
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6 The program delivers the contents in 14 units (most of them lasting 90 minutes) and in two
7 workshops (four to six class hours) that are evenly distributed over the grades five and six. In
8 detail, each lesson covers a specific topic, for instance problem solving, critical thinking,
9 effective communication skills, decision-making, interpersonal relationship skills, self-
10 awareness building skills, empathy, coping with stress, and emotions as well as the student's
11 ability to work in a group. The two workshops include several activities about smoking
12 cigarettes and alcohol misuse, and are designed as a student's course with nine challenging
13 stations that either address different aspects of smoking cigarettes or aspects of alcohol
14 misuse. Stations concerning the first workshop, smoking cigarettes, cover risks and
15 disadvantages of smoking, smoking related knowledge, perceived norms, and self-efficacy to
16 refuse a cigarette offers as well as strategies of advertisement and industry. The stations of
17 the second workshop deal with the same issues, but tailored to the topic of alcohol misuse.
18 All components are realized by trained teachers within daily school-routine. Further details on
19 the program have been described elsewhere.²⁰
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29 **Design**

30 A five-wave cluster randomized-controlled trial with two arms (intervention and control
31 condition) is being conducted in four German federal states (Bremen, Hesse, North Rhine-
32 Westphalia and Schleswig-Holstein) to evaluate the effects of "Eigenständig werden 5+6".
33 The randomization occurred at school level to avoid information exchange between
34 conditions in the school. For randomization, schools were stratified according to the following
35 criteria: (1) study region, (2) type of school, (3) number of fifth grade classes per school.
36 According to these strata, schools were randomly assigned to the two arms of the study with
37 a 50 per cent chance of being allocated to either group by using coin toss method.
38 Intervention group took part in "Eigenständig werden 5+6" and is compared to control group
39 receiving education as usual, i.e. lessons and subjects following the standard school
40 curriculum without specific interventions to foster life skills or to prevent smoking. Baseline
41 assessment took place prior to the intervention in October/November 2010, post-tests were
42 realized in June/July 2011 and June/July 2012, a 6-month follow-up was being conducted in
43 December 2012 and a 15-month follow-up will take place in September/October 2013. For
44 further details, see Hansen et al.²⁰
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55 **Study Sample**

56 A priori sample size determination assuming a significance level of $\alpha=0.05$, power=0.80, a
57 15% prevention effect, an average cluster size of 20 students per class, an intra class
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3 correlation of 0.02 and a drop-out rate of 25% revealed a recommended sample size of 158
4 classes and 3,160 students at baseline (for detailed description of sample size determination
5 see²⁰). To recruit the sample, complete lists of all secondary schools of selected regions
6 were obtained from the Ministries of Education of each federal state. An overall of 450
7 secondary schools in the study regions were invited to participate in the study, of which 323
8 (71.5%) did neither express approval or disapproval (Figure 1). The decision to participate in
9 the study was expressed by 48 schools (11%) with 191 classes and 4,772 students. Of these
10 48 schools agreeing to participate, 26 schools with 97 classes and 2,437 students were
11 allocated to the intervention group whereas 22 schools with 94 classes and 2,335 students
12 were assigned to the control condition. After randomization, three schools of the intervention
13 group withdrew their consent as well as four teachers of intervention classes refused to take
14 part.
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23 Consequently, baseline data comprise 45 schools, 172 classes and 3,444 students with a
24 mean age of 10.37 years (SD=0.59), 47.9% girls; with 1,685 students in 81 classes in the
25 intervention and 1,759 students in 91 classes in the control condition. In respect to different
26 outcome and covariate characteristics, intervention and control students were extensively
27 comparable with the exception of a higher proportion of students of Gymnasiums in the
28 control condition (for detailed baseline sample description see²⁰). Data presented herein refer
29 to the baseline (October 2010) and 6-month follow-up survey (December 2012). It was
30 possible to merge follow-up data of 1,255 students in the intervention arm and 1,438
31 students in the control arm (total N=2,693, 78.2% of N=3,444) to baseline data. For analysis,
32 data sets with inconsistencies concerning age, gender, and smoking status were excluded
33 (N=180). The final analysis sample consists of 2,513 data sets (intervention group: N=1,179,
34 control group: N=1,334). Mean age at follow-up was 12.50 years (SD=0.58).
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46 Measures

47 Data were collected through self-completed anonymous questionnaires by teachers and
48 students. The development of the questionnaire and a complete list of variables and
49 constructs assessed in the trial have been documented.²⁰ Analyses presented herein, rely on
50 the following outcome measures: *Lifetime tobacco smoking* experience was assessed by
51 asking how many cigarettes have ever been smoked in life. Nine answering categories
52 ('none', 'only a few puffs', '1 cigarette', '2 cigarettes', '3-4 cigarettes', '5-9 cigarettes', '10-19
53 cigarettes', '20-100 cigarettes', '>100 cigarettes') were provided. Students having smoked at
54 least a few puffs were considered as ever smokers. *Smoking incidence* at follow-up among
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3 baseline never smokers was determined by combining the answers to lifetime smoking at
4 baseline and follow-up: those who had never smoked at baseline, and indicated any smoking
5 by the follow-up survey, even just a few puffs, were considered as having initiated smoking
6 during the observation period. *Current smoking* frequency was measured by asking how
7 many cigarettes are currently smoked. Respondents could answer 'I don't smoke,' 'less than
8 once a month', 'at least once a month, but not weekly', 'at least once a week, but not daily,'
9 or 'daily'. Responses were dichotomized into students not smoking and students indicating
10 any kind of current smoking.
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16 To assess *attitudes towards smoking and risk perception*, respondents should rate eleven
17 statements (e.g. 'Non-smokers are fitter', 'Non-smokers are cooler', 'If I smoke during the
18 next month, I will get in trouble with my friends'). Answer categories comprise 0='not true',
19 1='somewhat true', 2='rather true', and 3='totally true', i.e. higher values represent a more
20 negative attitude towards smoking and more sensitive perception of risk. Cronbach's Alpha
21 of this scale was 0.80. A change in attitude from baseline to follow-up was determined by
22 subtracting the baseline value from the follow-up value for each respondent. *Smoking related*
23 *knowledge* was tested through seven statements (e.g. 'Cigarettes contain arsenic which is
24 also found in rat poison.') to which respondents could either agree by answering 'true' or
25 disagree by stating 'wrong' or state 'I don't know'. As indicator of knowledge, the percentage
26 of correct classifications of statements was determined. An increase in knowledge from
27 baseline to follow-up was determined by subtracting the baseline value from the follow-up
28 value for each respondent. *Normative expectations* were measured on an 11-point scale
29 ranging from 0='nobody' to 10='everybody' on which students had to estimate how many a)
30 'Adults in Germany' and b) 'Adolescents at their age' in Germany smoke. *Self-efficacy* to
31 refuse cigarette offers were assessed by asking 'To what extent do you dare to refuse
32 cigarettes, even if your friends laugh at you or suspend you on that account?' with answer
33 categories ranging from 0='not at all' to 3='totally'. Normative expectations and self-efficacy
34 were analyzed on single item level.
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47 *Covariate measures* were derived from studies that focused on risk factors of adolescent
48 tobacco use, to control for confounding variables that would be theoretically related to the
49 smoking measures.²¹⁻²³ Sociodemographics include age, gender, type of school (Gymnasium
50 vs. other type of school), migration background (mother and/or father were born outside
51 Germany) and socio-economic status (SES, Family Affluence Scale²⁴). As personal
52 characteristics, rebelliousness and sensation-seeking were assessed with two items in each
53 case.^{25,26} Parent, sibling and peer smoking were assessed as factors from social
54 environment (no vs. any parent/sibling/peer smoking). Finally, students were asked whether
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3 they had participated in a comprehensive prevention program in elementary school with
4 examples of most broadly disseminated programs given.
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7 8 **Procedure**

9 In schools having agreed to participate, teachers of the respective fifth grade collected the
10 parental informed consent. Students with refusal were excluded from all assessments. Data
11 assessment was conducted in the class room and lasted 45 minutes. Research staff was
12 responsible for the distribution, help in completion and collection of the questionnaire. To
13 permit a linking of individual baseline and follow-up data while assuring anonymity, students
14 generated a seven digit individual code. This procedure has been tested and used in several
15 studies and therefore been inspected and approved by Ethics Committee, data protection
16 and Ministries of Education repeatedly.²⁷ Teachers were not involved in the data
17 assessment. At the end of the assessment, all questionnaires were placed in an envelope
18 which was sealed in front of the class. Therefore, every student was assured that neither
19 teachers nor parents were able to see the completed questionnaire.
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27 Ethical approval for the trial was gained from the Ethics Committee of Medical Faculty of the
28 University of Kiel. Additional approvals (e.g., from ministries of education, and parents) were
29 sought as required.
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33 **Analyses**

34 Predictors of attrition were examined by multilevel mixed effect logistic regressions. To test
35 for selective attrition, interaction effects for group condition and dependent variable were
36 tested. Descriptive statistics (percentages, means, standard deviations) are crude values. To
37 analyze the effects of the intervention on smoking behavior as well as on attitudes and
38 knowledge, multilevel mixed effect regression models using Stata *mixed* and *meqrlogit*
39 command were conducted, adjusting for covariates. In case of dichotomous outcomes, effect
40 sizes (Cohen's d) were determined by using the converting formula proposed by Borenstein
41 et al.²⁸ Effect sizes for metric outcomes were calculated as proposed by Feingold.²⁹ All data
42 analyses were conducted with Stata V.13.³⁰
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50 **RESULTS**

51 **Attrition analysis**

52 Among the 3,444 students assessed at baseline, there were no data available in the analysis
53 sample for 931 students (27.0%). Overall, significantly higher attrition was found for male
54 students (31.2%; $p<0.001$), students with a migration background (36.5%; $p<0.001$), students
55 indicating current smoking (45.7%; $p=0.047$) or current use of alcohol (39.8%; $p<0.001$) at
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3 baseline. Furthermore, students dropping out of the study were older than students in the
4 retention sample ($M_{\text{attrition}}=10.5$ vs. $M_{\text{retention}}=10.3$ years of age at baseline; $p=0.003$). Besides
5 these overall effects, no hints for selective attrition were found, i.e. the associations between
6 variables listed above and attrition did not differ systematically between the intervention and
7 control group.
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10 11 **Effects on smoking behavior**

12 Students in the intervention and control group did not differ in rates for lifetime and current
13 smoking at baseline. At follow-up, 16.0% of intervention students indicated that they had ever
14 smoked in their lives compared to 20.2% in the control students (Figure 2). This difference
15 was statistically significant also after controlling for confounding factors (adjusted Odds Ratio
16 [OR]=0.63; 95% confidence interval [CI]=[0.41; 0.96]; $p=0.026$).
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19 While about 1% of intervention and control students reported current smoking at baseline,
20 these rates increased to more than 5% at follow-up both in intervention and control group.
21 Therefore, no group differences could be found in the frequency of current smoking.
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24 At baseline, 95.6% of the sample were never-smokers ($N=2,403$; intervention group: 96.4%,
25 control group: 94.9%). Among these baseline never-smokers, 15.5% initiated smoking during
26 the observation period. The incidence rate was significantly lower in intervention students,
27 among whom 13.7% reported the first use of cigarettes between baseline and follow-up,
28 compared to the control group with an incidence rate of 17.1% (adjusted OR=0.66, 95%
29 CI=[0.43; 1.00], $p=0.047$).
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42 **Effects on smoking related knowledge and attitudes**

43 Students of both groups showed about the same level of smoking related knowledge at
44 baseline with correct answering rates of about 30% (Table 1). At follow-up, students in both
45 groups scored better in the knowledge test: intervention students had a mean percentage of
46 correct answers of 46.75, while the control students rated on average 37.74% of the
47 statements correctly. The increase in knowledge was significantly higher in the intervention
48 group (adjusted $\beta=9.38$; 95% CI=[6.73; 12.04]; $p<0.001$).
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3 A comparable pattern was found for attitudes towards smoking: At baseline, both groups did
4 not differ in their attitudes and showed a rather critical perception of smoking with a mean
5 score of 2.04 on the scale ranging from 0 to 3 (Table 1). At follow-up, students rated smoking
6 even more negatively with a mean score of 2.24 in the intervention and 2.16 in the control
7 group. Compared to the control group, this change in attitudes was more pronounced in the
8 intervention group (adjusted $\beta=0.10$; 95% CI=[0.03; 0.16]; $p=0.002$).
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13 Normative expectations were hardly influenced by the intervention: While intervention
14 students estimated smoking prevalence in adults marginally lower at follow-up compared to
15 their estimation at baseline, a small increase in this estimate could be observed in control
16 students (Table 1). For peer smoking, both groups showed a small increase in perceived
17 frequency of smoking. None of these changes turned out to be statistically significant after
18 covariates and baseline estimates were controlled for.
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24 Already at baseline, students in both groups considered themselves rather capable to refuse
25 cigarette offers (Table 1). During the observation period, self-efficacy even grew with a
26 slightly higher – but statistically insignificant – increase in intervention students compared to
27 control students.
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Table 1.

Descriptive statistics and multilevel mixed effects linear regressions for smoking related knowledge, attitudes, perceived norms and self-efficacy to refuse cigarette offers

	Baseline		Follow-up		Change		Difference in change		
	Beginning of grade 5		Mid of grade 7		Intervention	Control	adj. β^1	95% CI	p
	Intervention	Control	Intervention	Control					
	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)			
Knowledge ²	30.34 (19.47)	30.11 (19.14)	46.75 (21.59)	37.74 (20.45)	16.53 (26.46)	7.53 (24.13)	9.38	6.73; 12.04	<0.001
Attitudes/risk perception ³	2.04 (0.51)	2.04 (0.51)	2.24 (0.51)	2.16 (0.54)	0.20 (0.61)	0.12 (0.61)	0.10	0.03; 0.16	0.002
Norms adult smoking ⁴	6.08 (1.62)	5.97 (1.59)	6.04 (1.62)	6.09 (1.55)	-0.03 (2.09)	0.12 (1.95)	-0.08	-0.24; 0.07	0.265
Norms peer smoking ⁴	3.08 (2.64)	2.93 (2.56)	4.24 (2.28)	4.02 (2.18)	1.16 (3.10)	1.10 (2.93)	0.15	-0.13; 0.43	0.283
Self-efficacy to refuse cigarettes ⁵	2.38 (1.04)	2.36 (1.03)	2.53 (0.80)	2.49 (0.85)	0.15 (1.20)	0.11 (1.22)	0.07	-0.03; 0.17	0.140

M = Mean, SD = Standard deviation, CI = Confidence interval

¹ Adjusted for age, gender, type of school, socio-economic status, immigration background, peer / parent / sibling smoking, sensation seeking, rebelliousness, earlier participation in a prevention program, baseline value of the respective variable

² Mean percentage of correct answers in a 7-item quiz

³ Range 0 to 3, higher values representing more negative attitude

⁴ Range 0 = nobody smokes to 10 = everybody smokes

⁵ Range 0-3, higher values representing higher self-efficacy

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3 Effect sizes for significant program effects were small to medium with $d=0.26$ (lifetime
4 smoking), $d=0.23$ (incidence of smoking), $d=0.45$ (smoking related knowledge), and $d=0.15$
5 (attitudes/risk perception).
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8 9 **Sensitivity analyses**

10 Since a substantial proportion of cases was excluded from the analysis sample due to
11 inconsistent data ($N=180$) or as they were lost to follow-up ($N=931$), we conducted some
12 sensitivity analyses to estimate the risk that the findings might be biased by these exclusions.
13 First, we reran the analyses with inconsistent cases left in the dataset. This re-inclusion of
14 inconsistent cases hardly changed the results for metric outcomes with significant effects for
15 knowledge and attitudes and slightly changed results for smoking behavior with marginally
16 significant associations for lifetime smoking ($p=0.086$) and incidence ($p=0.083$). To address
17 the restriction of sample to complete cases, predictors for higher attrition were used as guide
18 to create subsamples. As the attrition rate was highest in baseline current smokers and
19 therefore this (small) subgroup of students smoking already very early might differ
20 substantially from the majority of non-smoking students, we excluded baseline current
21 smokers ($N=25$) completely. For this subsample, we found the same significant effects for
22 lifetime smoking ($p=0.030$), knowledge ($p<0.001$) and attitudes ($p=0.002$) and no effects on
23 current smoking, norms and self-efficacy. Further factors being associated with a higher risk
24 of attrition (male gender, higher age, migration background) were explored by analyzing
25 subsamples of male students, students aged ≥ 11 years at baseline and students with
26 migration background. In these subsamples, incidence rates in control students exceeded
27 those of intervention by 4 to 7 percent points (reaching significance for older students,
28 $p=0.026$, marginal significance for students with migration background, $p=0.061$, and failing
29 to reach significance for male students, $p=0.225$).
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42 43 **DISCUSSION**

44 The current study aimed to investigate the effects of a school-based prevention program on
45 smoking related knowledge, attitudes and behavior six months after the end of program
46 implementation. Using a cluster randomized controlled design, findings revealed that the
47 program participation seems to reduce the prevalence and incidence of lifetime smoking, to
48 increase smoking related knowledge, and to influence attitudes and perceived risks of
49 smoking towards a more critical perception. Program effects on the prevalence of current
50 smoking, normative expectations or refusal skills could not be determined. Using Cohen's
51 classification of effect sizes,³¹ effect size was small for smoking behavior and attitudes, while
52 there was a medium effect on smoking related knowledge.
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3 The pattern found for effects on smoking behavior with significant small effects on smoking
4 incidence ($d=0.23$) and lifetime smoking ($d=0.26$), and no effect on current smoking can be
5 aligned quite well with the results presented in former meta-analyses: The pooled odds ratio
6 of 0.88 for smoking onset at the longest follow-up revealed by the overall analysis of Thomas
7 et al.¹³ corresponds to an effect size of $d=0.07$, while their subgroup analyses for different
8 intervention approaches provided even moderate effect sizes (odds ratios between 0.49 and
9 0.52 corresponding to d 's between 0.36 and 0.39). Earlier meta-analyses on school-based
10 drug prevention programs,¹⁴ psychosocial smoking prevention programs¹⁵ or studies on
11 Project DARE (Drug Abuse Resistance Education),¹⁶ the most widely used school-based
12 drug prevention program in the United States and focusing on teaching skills to recognize
13 and resist social pressure, also determined small program effects on substance use with d 's
14 ranging between 0.08 and 0.18. Finding no effect on current smoking might also be
15 explained to some extent by the young age of the sample with only very few students
16 smoking already on a regular basis.
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26 The participation in "Eigenständig werden 5+6" significantly increased smoking related
27 knowledge with an effect size of $d=0.45$ – the highest effect found in our analyses. This
28 medium effect is in line with effect sizes ranging from 0.36 to 0.42 determined in meta-
29 analyses referred to above.¹⁴⁻¹⁶ Attitudes were influenced also significantly by the
30 intervention, the small effect ($d=0.15$) compares well with the small effects in a range from
31 0.11 to 0.26 having been reported.¹⁴⁻¹⁶
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36 We were not able to show an effect of the intervention in correcting perceived norms of
37 smoking or in enhancing self-efficacy to refuse offered cigarettes. Students of both
38 intervention and control group consider themselves to be rather highly self-efficacious to
39 resist to cigarette offers already at the outset of the study and this rating even increases in
40 both groups at follow-up, i.e. a ceiling effect might decrease the discriminative power of the
41 group comparisons. As far as perceived norms of smoking are concerned, a possible
42 explanation of the null-effect is the fact that only a minor part of the intervention (one subtask
43 among nine tasks of the smoking workshop at the end of grade 5) deals with the topic of
44 norms. Most tasks in the workshop address facts about and visualization of the short- and
45 long-term consequences of smoking, others aim to scrutinize strategies of the tobacco
46 industry or to foster resistance skills.
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54 Some limitations of the current study have to be considered: During the 26 month period
55 from baseline to follow-up, there has been some drop-out from the study. The analysis
56 sample ($N=2,513$) amounted to 73.0% of the baseline sample ($N=3,444$). This drop-out was
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3 slightly higher than expected in the a priori power calculation (25%), but since the baseline
4 sample was somewhat larger than calculated (N=3,444 instead of N=3,160), the analysis
5 sample still exceeds the estimated sample at follow-up (75% of 3,160 = 2,370). Therefore,
6 the power of the analyses should be adequate. Furthermore, we did not find any hints for
7 selective attrition which could restrict the validity of findings and sensitivity analyses revealed
8 very comparable patterns of results in subsamples with higher risk for attrition and smoking.
9 The curriculum "Eigenständig werden 5+6" comprises of 14 lessons à on average 90 minutes
10 and two workshops with 4 to 6 hours of duration which are implemented by teachers in
11 addition to usual education, i.e. the program is quite time-consuming, it requires some
12 dedication by teachers and it seems unreasonable to assume that the intervention is
13 delivered to all classes exactly in the way and to the extent foreseen by the manual. The
14 analyses in this report were not controlled for treatment integrity,^{32,33} i.e. classes with low
15 treatment fidelity that have only been exposed to parts of the intervention contribute to the
16 same extent to the results of the intervention group as classes with complete program
17 implementation. Therefore, results can be considered as rather conservative. Another
18 limitation is the reliance on self-reports in the assessment of outcomes. Especially for
19 outcomes assessing smoking behavior, but also for attitudes towards smoking, answers
20 might be biased by social desirability. These influences might occur more likely in the
21 intervention group since students might be primed by the intervention that smoking is an
22 "unwanted" behavior. Nevertheless, since purchase of cigarettes and smoking in public is
23 forbidden by law for minors in Germany, students in the control condition are not free of a
24 social desirability bias as well. For other outcomes like the assessment of refusal skills,
25 validity of self-report data might be limited by restricted accessibility, i.e. whether adolescents
26 are really able to judge their own competence to resist cigarette offers. Finally, the study was
27 run in regular public schools of four federal states of Germany, i.e. the generalizability might
28 be limited due to these regional constraints and restricted to adolescents visiting regular
29 schools.
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46 On the other hand, some strengths of the current study should be born in mind: Results were
47 derived from a cluster randomized controlled trial, applying sophisticated statistical methods,
48 comprising a range of several outcomes and following students up for six months after the
49 end of intervention. Therefore, we implemented rather rigorous evaluation methods, which
50 are in line with recommendations like those of the Society for Prevention Research.³⁴
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55 Perspectives and open questions for future research might be the following: In the current
56 trial, a further follow-up at 15 months after end of intervention is being conducted to explore
57 stability of effects in the longer term. Furthermore, exploring effects on other outcomes than
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3 smoking, e.g. alcohol use or life skills, is owing for the current study. On the basis of findings
4 for efficacy, effectiveness in relation to costs as well as generalizability to other populations
5 should be investigated. Finally, besides stating whether an intervention is effective or not,
6 mechanisms by which shown effects can be explained theoretically and empirically are to be
7 explored. These mediation analyses may contribute to investigate causal models for
8 preventive intervention, e.g. to explore whether knowledge or change in attitude are
9 necessary preconditions for behavior change.¹⁴
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For peer review only

Figure legends

Figure 1. Participation flowchart

Figure 2. Percentage of lifetime smoking, current smoking at baseline and 6-month follow-up, percentage of smoking incidence at 6-month follow-up among baseline never-smokers, and multilevel mixed effects logistic regressions; OR = odds ratio, CI = confidence interval; logistic regressions were adjusted for age, gender, type of school, socio-economic status, immigration background, peer / parent / sibling smoking, sensation seeking, rebelliousness, earlier participation in a prevention program

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Competing interests

None.

Ethics approval

Ethics approval was provided by the Ethics Committee of the Medical Faculty of the University of Kiel (Ref.: D 419/10).

Contributors

BI performed the statistical analysis and interpretation of the data and drafted the manuscript. JH contributed to the acquisition of the data and participated in drafting the manuscript. KM contributed to the acquisition and management of the data. RH as principle investigator is responsible for the study concept, design and supervision and helped in drafting the manuscript.

All authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors conducted a critical revision of the article and granted final approval of the article for important intellectual content.

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Data sharing statement

No additional data available.

For peer review only

References

- (1) Lim SS, Vos T, Flaxman AD, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2013; 380(9859):2224-2260.
- (2) Bundeszentrale für gesundheitliche Aufklärung. Der Tabakkonsum Jugendlicher und junger Erwachsener in Deutschland 2012. Ergebnisse einer aktuellen Repräsentativbefragung und Trends. Köln: Bundeszentrale für gesundheitliche Aufklärung; 2013.
- (3) Robert Koch-Institut. Die Gesundheit von Kindern und Jugendlichen in Deutschland. Berlin: Robert Koch-Institut; 2013.
- (4) World Health Organisation. Life skills education in schools, parts 1 and 2. Geneva: WHO, Division of Mental Health; 1994.
- (5) Evans RI. Smoking in children: developing a social psychological strategy of deterrence. *Prev Med* 1976; 51:122-127.
- (6) Donaldson SI, Graham JW, Hansen WB. Testing the generalizability of intervening mechanism theories: understanding the effects of adolescent drug use prevention interventions. *J Behav Med* 1994; 17(2):195-216.
- (7) Flay BR. The promise of long-term effectiveness of school-based smoking prevention programs: a critical review of reviews. *Tob Induc Dis* 2009; 5(1):7.
- (8) Cuijpers P. Effective ingredients of school-based drug prevention programs. A systematic review. *Addict Behav* 2002; 27(6):1009-1023.
- (9) Gottfredson DC, Wilson DB. Characteristics of effective school-based substance abuse prevention. *Prev Sci* 2003; 4(1):27-38.
- (10) Flay BR. School-based smoking prevention programs with the promise of long-term effects. *Tob Induc Dis* 2009; 5(1):6.
- (11) Skara S, Sussman S. A review of 25 long-term adolescent tobacco and other drug use prevention program evaluations. *Prev Med* 2003; 37(5):451-474.
- (12) Wiehe SE, Garrison MM, Christakis DA, et al. A systematic review of school-based smoking prevention trials with long-term follow-up. *J Adolesc Health* 2005; 36(3):162-169.
- (13) Thomas RE, McLellan J, Perera R. School-based programmes for preventing smoking. *Cochrane Database Syst Rev* 2013; 4:CD001293.
- (14) Tobler NS, Stratton HH. Effectiveness of school-based drug prevention programs: a meta-analysis of the research. *J Prim Prev* 1997; 18(1):71-128.

- 1
2
3 (15) Hwang MS, Yeagley KL, Petosa R. A meta-analysis of adolescent psychosocial
4 smoking prevention programs published between 1978 and 1997 in the United
5 States. *Health Educ Behav* 2004; 31(6):702-719.
6
7 (16) Ennett ST, Tobler NS, Ringwalt CL, et al. How effective is drug abuse resistance
8 education? A meta-analysis of Project DARE outcome evaluations. *Am J Public*
9 *Health* 1994; 84(9):1394-1401.
10
11 (17) Müller-Riemenschneider F, Rasch A, Bockelbrink A, et al. Effectiveness and cost-
12 effectiveness of behavioural strategies in the prevention of cigarette smoking. *GMS*
13 *Health Technol Assess* 2008; 4:Doc10.
14
15 (18) Cuijpers P. Three decades of drug prevention research. *Drug Educ Prev Polic* 2003;
16 10(1):7-20.
17
18 (19) Hansen WB, Dusenbury L, Bishop D, et al. Substance abuse prevention program
19 content: systematizing the classification of what programs target for change. *Health*
20 *Educ Res* 2007; 22(3):351-360.
21
22 (20) Hansen J, Hanewinkel R, Maruska K, et al. The 'Eigenständig werden' prevention
23 trial: a cluster randomised controlled study on a school-based life skills programme to
24 prevent substance use onset. *BMJ Open* 2011; 1(2):e000352.
25
26 (21) Gibbons FX, Gerrard M. Predicting young adults' health risk behavior. *J Pers Soc*
27 *Psychol* 1995; 69(3):505-517.
28
29 (22) Hawkins JD, Catalano RF, Miller JY. Risk and protective factors for alcohol and other
30 drug problems in adolescence and early adulthood: implications for substance abuse
31 prevention. *Psychol Bull* 1992; 112(1):64-105.
32
33 (23) Petraitis J, Flay BR, Miller TQ. Reviewing theories of adolescent substance use:
34 organizing pieces in the puzzle. *Psychol Bull* 1995; 117(1):67-86.
35
36 (24) Currie C, Molcho M, Boyce W, et al. Researching health inequalities in adolescents:
37 the development of the Health Behaviour in School-Aged Children (HBSC) family
38 affluence scale. *Soc Sci Med* 2008; 66(6):1429-1436.
39
40 (25) Stephenson MT, Hoyle RH, Palmgreen P, et al. Brief measures of sensation seeking
41 for screening and large-scale surveys. *Drug Alcohol Depend* 2003; 72(3):279-286.
42
43 (26) Burt RD, Dinh KT, Peterson Jr AV, et al. Predicting adolescent smoking: a
44 prospective study of personality variables. *Prev Med* 2000; 30(2):115-125.
45
46 (27) Galanti MR, Siliquini R, Cuomo L, et al. Testing anonymous link procedures for
47 follow-up of adolescents in a school-based trial: The EU-DAP pilot study. *Prev Med*
48 2007; 44(2):174-177.
49
50 (28) Borenstein M, Hedges LV, Higgins JPT, et al; Introduction to meta-analysis.
51 Chichester: Jon Wiley & Sons; 2009.
52
53 (29) Feingold A. Effect sizes for growth-modeling analysis for controlled clinical trials in the
54 same metric as for classical analysis. *Psychol Methods* 2009; 14(1):43-53.
55
56 (30) StataCorp. Stata Statistical Software: Release 13. College Stations, Texas:
57 StataCorp; 2013.
58
59
60

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2
3 (31) Cohen J. Statistical power analyses for behavioral science. Hilldale, New York:
4 Erlbaum; 1988.
5
6 (32) Bishop DC, Pankratz MM, Hansen WB, et al. Measuring Fidelity and Adaptation:
7 Reliability of a Instrument for School-Based Prevention Programs. *Eval Health Prof*
8 2013.
9
10 (33) Dusenbury L, Brannigan R, Falco M, et al. A review of research on fidelity of
11 implementation: implications for drug abuse prevention in school settings. *Health*
12 *Educ Res* 2003; 18(2):237-256.
13
14 (34) Flay BR, Biglan A, Boruch RF, et al. Standards of evidence: criteria for efficacy,
15 effectiveness and dissemination. *Prev Sci* 2005; 6(3):151-175.
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Effects of a School-Based Prevention Program on Smoking [in early Adolescence](#): Six-Month Follow-up of the 'Eigenständig werden' Cluster Randomized Trial

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Key words: smoking; school-based prevention; cluster randomized controlled trial; efficacy

Word count main text: [3,7704.398](#)

ABSTRACT

Objectives: To test the effects of a school-based prevention program on students' smoking related behavior, attitudes and knowledge six months after ~~program~~ implementation over two school-years has ended.

Design: Two-arm prospective cluster randomized controlled trial with a follow-up survey six months after end of program implementation, i.e. 26 months after baseline.

Setting: Forty-five public secondary schools from four federal states in Germany (Bremen, Hesse, North Rhine-Westphalia, Schleswig-Holstein).

Participants: A total of 3,444 students from 172 classes at baseline with a mean age of 10.37 years (SD=0.59) and 47.9% girls at baseline. Analysis sample with follow-up data merged to baseline data comprises 2,513 data sets (73.0%).

Intervention: "Eigenständig werden 5+6", a school-based prevention program for grade five and six to enhance substance specific and general life skills, consisting of 14 units (à 90 minutes) and two workshops (4 ~~resp.~~ 6 hours) being taught over a time period of two school- years by trained teachers.

Outcome measures: Lifetime and current smoking, incidence of smoking in baseline never smokers, smoking related knowledge, attitudes, perceived norms of smoking, self-efficacy to refuse cigarette offers were assessed in students.

Results: Six months after end of program implementation, students of intervention classes showed significantly lower rates for lifetime smoking (adjusted odds ratio [OR]=0.63;95% confidence interval [CI]=[0.41; 0.96];p=0.026) and incidence of smoking (adjusted OR=0.66; 95%CI=[0.43; 1.00];p=0.047), a higher increase of smoking related knowledge (adjusted β =9.38; 95%CI=[6.73; 12.04];p<0.001) and a greater change in attitudes towards a more critical perception of risks and disadvantages of smoking (adjusted β =0.10; 95%CI=[0.03; 0.16];p=0.002). No group differences were found for current smoking, perceived norms of smoking and self-efficacy to refuse cigarette offers.

Conclusions: Participation in the school-based prevention program "Eigenständig werden 5+6" may have small effects on smoking behavior and attitudes and a moderate effect on smoking related knowledge.

Trial registration: Current Controlled Trials ISRCTN99442407

Word count abstract: 298 words

ARTICLE SUMMARY

Article focus

- School-based prevention programs show inconsistent results concerning efficacy and most of evaluation studies were conducted in the US.
- This study investigates the effects of a prevention program implemented in grade-5 and 6 young adolescents in German schools on different outcomes six months after the end of the two school-years lasting program implementation using rigorous evaluation methodology.

Key messages

- Program participation seems to reduce the prevalence and incidence of lifetime smoking, to increase smoking related knowledge, and to influence attitudes towards a more critical perception of smoking.

Strengths and limitations of this study

- Findings were retrieved from a cluster randomized controlled trial with a well-powered sample and under usage of sophisticated statistical methods controlling for confounders and taking clustering of data into account.
- Drop out, reliance on self-reports and lack of control for treatment integrity may be limiting factors to this study.

BACKGROUND

Smoking remains to be the single greatest preventable cause of mortality worldwide, being a major risk factor for a number of life-threatening diseases, including various cancers, cardiovascular diseases and lung diseases.¹ Though reductions in smoking rates in adolescents have been documented for many Western countries including Germany² over the last decade, smoking prevention is still a main issue for public health. Most recent data from Germany reveal smoking rates of about 12% for both female and male adolescents aged 12 to 17 years and 6.6% for young adolescents aged 12 to 15 years.^{2,3}

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School programs are often one of the first approaches mentioned in efforts to denormalize tobacco use and to raise awareness of tobacco's hazardous nature. Prominent approaches to prevent smoking in students are the development and improvement of general life skills, as well as the fostering of skills for resisting social influence and substance-specific skills in adolescence. General life skills are considered to empower adolescents in challenging situations and to help them to master life as competent as possible.^{4,5} By enhancing these skills, it is assumed to prevent substance use and abuse, since substance use is considered as a dysfunctional strategy to cope with every day challenges and developmental tasks in adolescence. In line with the social influence approach,^{5,6} smoking is conceptualized as a result of influences emerging from the adolescent's environment like peers, family, or media by normative processes and/or overt cigarette offers. Therefore, correction of inaccurate norms is one important component of these programs to adjust the often overestimated prevalence of smoking in adolescence towards more conservative and realistic norms.^{6,7} Skill training following these approaches is considered to 'inoculate' students against influences encouraging them to smoke, to help them resist temptations from peers to smoke and to correct normative expectations towards smoking.

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For more than 40 years prevention programs have been implemented and evaluated within the school setting. However, the empirical evidence of the efficacy of these approaches is not yet uniquely convincing.^{7-12,6-14} A recent Cochrane review on the effects of school-based smoking prevention trials^{13,12} selected randomized controlled trials where students, classes, schools, or school districts were randomized to intervention arm(s) versus a control group, and followed-up for at least six months. One hundred and thirty-four studies involving 428,293 participants met the inclusion criteria of the review which revealed an overall significant intervention effect on the onset of smoking at longest follow-up, while there was no overall effect at follow-ups at one year or less. When analyzing intervention effects not only on smoking behavior, but also on further outcomes addressed directly or indirectly by school-based interventions like attitudes towards smoking, resistance skills or smoking

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7 related knowledge, findings might be condensed into a more or less consistent pattern with
8 medium effects being found for knowledge and, if any, small effects for attitudes, skills and
9 use.^{14-16,13-15}

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11 Among altogether 37 trials on smoking prevention strategies from the time period 2001 to
12 2006 which were included in a Health Technology Assessment, only one study originated
13 from Germany.^{17,46} The Cochrane Review^{13,42} which covers publications until 2012 included
14 another five studies from Germany, three of them were trials being published until 2000, and
15 two trials being published after 2006 (one of these was a multi-center study with one out of
16 seven centers being located in Germany). Most of these studies had some methodological
17 shortcomings like not adjusting for the clustering of data which results from the specific
18 characteristics of the setting with delivery of the intervention to complete classes, and
19 schools or classes instead of individuals being the unit of randomization. Therefore, a lack of
20 rigorous evaluation trials on smoking prevention programs can be inferred especially for
21 Germany.
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28 The present study aims to contribute to overcome shortcomings in the evidence for the
29 efficacy of school-based smoking prevention by presenting results of a cluster randomized
30 trial from Germany. We report findings on the 6-month follow-up effects of a school-based
31 curriculum named "Eigenständig werden 5+6" ("Becoming independent 5+6") for students in
32 grade five and six when they are about 10 to 12 years old. The overall aim of "Eigenständig
33 werden 5+6" is the prevention of substance use and abuse by increasing substance specific
34 skills and general life skills of students. Findings presented herein refer to effects of program
35 participation on smoking related knowledge, attitudes towards smoking, perceived norms of
36 smoking, self-efficacy to resist cigarette offers and actual smoking behavior six months after
37 end-of-the program implementation over two school-years has ended, i.e. on average 26
38 months after baseline.
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45 METHODS

46 Intervention

47 "Eigenständig werden 5+6" is a school-based prevention program for students in grade five
48 and six which takes quality criteria of effective prevention programs into account.^{8,9,18,19,7-9,17,18}
49 Based on the life skills approach and on the social influence model, "Eigenständig werden
50 5+6" aims primarily at the prevention of substance use (i.e. tobacco smoking and drinking
51 alcohol) by increasing general life skills as well as substance specific skills (i.e. coping with
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emotions, stress, problems, pressures to smoke and drink alcohol, increase of refusal skills and decrease of susceptibility to pro-smoking and pro-alcohol social influences).

The program delivers the contents in 14 units (most of them lasting 90 minutes) and in two workshops (four to six class hours) that are evenly distributed over the grades five and six. In detail, each lesson covers a specific topic, for instance problem solving, critical thinking, effective communication skills, decision-making, interpersonal relationship skills, self-awareness building skills, empathy, coping with stress, and emotions as well as the student's ability to work in a group. The two workshops include several activities about smoking cigarettes and alcohol misuse, and are designed as a student's course with nine challenging stations that either address different aspects of smoking cigarettes or aspects of alcohol misuse. Stations concerning the first workshop, smoking cigarettes, cover risks and disadvantages of smoking, smoking related knowledge, perceived norms, and self-efficacy to refuse a cigarette offers as well as strategies of advertisement and industry. The stations of the second workshop deal with the same issues, but tailored to the topic of alcohol misuse.~~The program delivers the contents (life skills, students' ability to work in a group, substance specific skills) in 14 units (most of them lasting 90 minutes) and in two workshops (four to six class hours) that are evenly distributed over the grades five and six. Workshops include several activities about substance use such as smoking cigarettes and alcohol misuse.~~ All components are realized by trained teachers within daily school-routine. Further details on the program have been described elsewhere.²⁰¹⁹

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Design

A five-wave cluster randomized-controlled trial with two arms (intervention and control condition) is being conducted in four German federal states (Bremen, Hesse, North Rhine-Westphalia and Schleswig-Holstein) to evaluate the effects of "Eigenständig werden 5+6". The randomization occurred at school level to avoid information exchange between conditions in the school. For randomization, schools were stratified according to the following criteria: (1) study region, (2) type of school, (3) number of fifth grade classes per school. According to these strata, schools were randomly assigned to the two arms of the study with a 50 per cent chance of being allocated to either group by using coin toss method. Intervention group took part in "Eigenständig werden 5+6" and is compared to control group receiving education as usual, i.e. lessons and subjects following the standard school curriculum without specific interventions to foster life skills or to prevent smoking. ~~Baseline~~ aAssessments took place prior to the intervention in October/November 2010, post-tests were realized in June/July 2011 and June/July 2012, a 6-month follow-up was being

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7 conducted in December 2012 and a 15-month follow-up will take place in September/October
8 2013. For further details, see Hansen et al.²⁰⁴⁹

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10 Study Sample

11 A priori sample size determination assuming a significance level of $\alpha=0.05$, power=0.80, a
12 15% prevention effect, an average cluster size of 20 students per class, an intra class
13 correlation of 0.02 and a drop-out rate of 25% revealed a recommended sample size of 158
14 classes and 3,160 students at baseline (for detailed description of sample size determination
15 see²⁰). To recruit the sample, c~~Complete lists of all secondary schools of selected regions~~
16 were obtained from the Ministries of Education of each federal state. An overall of 450
17 secondary schools in the study regions were invited to participate in the study, of which 323
18 (71.5%) did neither express approval or disapproval (Figure 1). The decision to participate in
19 the study was expressed by 48 schools (11%) with 191 classes and 4,772 students. Of these
20 48 schools agreeing to participate, 26 schools with 97 classes and 2,437 students were
21 allocated to the intervention group whereas 22 schools with 94 classes and 2,335 students
22 were assigned to the control condition. After randomization, three schools of the intervention
23 group withdrew their consent as well as four teachers of intervention classes refused to take
24 part.

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32 Consequently, baseline data comprises ~~s~~ 45 schools, 172 classes and 3,444 students with a
33 mean age of 10.37 years (SD=0.59), 47.9% girls~~-;~~ with 1,685 students in 81 classes in the
34 intervention and 1,759 students in 91 classes in the control condition. In respect to different
35 outcome and covariate characteristics, intervention and control students were extensively
36 comparable with the exception of a higher proportion of students of Gymnasiums in the
37 control condition (for ~~sample size determination and~~ detailed baseline sample description
38 see²⁰⁴⁹). Data presented herein refer to the baseline (October 2010) and 6-month follow-up
39 survey (December 2012). It was possible to merge follow-up data of 1,255 students in the
40 intervention arm and 1,438 students in the control arm (total N=2,693, 78.2% of N=3,444) to
41 baseline data. For analysis, data sets with inconsistencies concerning age, gender, and
42 smoking status were excluded (N=180). The final analysis sample consists of 2,513 data sets
43 (intervention group: N=1,179, control group: N=1,334). Mean age at follow-up was 12.50
44 years (SD=0.58).

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53 Measures

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7 Data ~~was~~were collected through self-completed anonymous questionnaires by teachers and
8 students. ~~The d~~Development of ~~the~~ questionnaire and a complete list of variables and
9 constructs assessed in the trial have been documented. ²⁰¹⁹ ~~Analysis-Analyses~~ presented
10 herein, rely on the following outcome measures: *Lifetime tobacco smoking* experience was
11 assessed by asking how many cigarettes have ever been smoked in life. Nine answering
12 categories ('none', 'only a few puffs', '1 cigarette', '2 cigarettes', '3-4 cigarettes', '5-9
13 cigarettes', '10-19 cigarettes', '20-100 cigarettes', '>100 cigarettes') were provided. Students
14 having smoked at least a few puffs were considered as ever smokers. *Smoking incidence* at
15 follow-up among baseline never smokers was determined by combining ~~the~~ answers to
16 lifetime smoking at baseline and follow-up: those who had never smoked at baseline, and
17 indicated any smoking by the follow-up survey, even just a few puffs, were considered as
18 having initiated smoking during the observation period. *Current smoking* frequency was
19 measured by asking how many cigarettes are currently smoked. Respondents could answer
20 'I don't smoke,' 'less than once a month', 'at least once a month, but not weekly', 'at least
21 once a week, but not daily,' or 'daily'. Responses were dichotomized into students not
22 smoking and students indicating any kind of current smoking.
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29 To assess *attitudes towards smoking and risk perception*, respondents should rate eleven
30 statements (e.g. 'Non-smokers are fitter', 'Non-smokers are cooler', 'If I smoke during the
31 next month, I will get in trouble with my friends'). Answer categories comprise 0='not true',
32 1='somewhat true', 2='rather true', and 3= 'totally true', i.e. higher values represent a more
33 negative attitude towards smoking and more sensitive perception of risk. Cronbach's Alpha
34 of this scale was 0.80. ~~A c~~Change in attitude from baseline to follow-up was determined by
35 subtracting ~~the~~ baseline value from ~~the~~ follow-up value for each respondent. *Smoking related*
36 *knowledge* was tested through seven statements (e.g. 'Cigarettes contain arsenic which is
37 also found in rat poison.') to which respondents could either agree by answering 'true' or
38 disagree by stating 'wrong' or state 'I don't know'. As indicator of knowledge, ~~the~~ percentage
39 of correct classifications of statements was determined. ~~An i~~increase in knowledge from
40 baseline to follow-up was determined by subtracting ~~the~~ baseline value from ~~the~~ follow-up
41 value for each respondent. *Normative expectations* were measured on an 11-point scale
42 ranging from 0='nobody' to 10='everybody' on which students had to estimate how many a)
43 'Adults in Germany' and b) 'Adolescents at their age' in Germany smoke. *Self-efficacy* to
44 refuse cigarette offers were assessed by asking 'To what extent do you dare to refuse
45 cigarettes, even if your friends laugh at you or suspend you on that account?' with answer
46 categories ranging from 0='not at all' to 3='totally'. Normative expectations and self-efficacy
47 were analyzed on single item level.
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Covariate measures were derived from studies that focused on risk factors of adolescent tobacco use, to control for confounding variables that would be theoretically related to the smoking measures.^{21-23,20-22} Sociodemographics include age, gender, type of school (Gymnasium vs. other type of school), migration background (mother and/or father were born outside Germany) and socio-economic status (SES, Family Affluence Scale^{24,23}). As personal characteristics, rebelliousness and sensation-seeking were assessed with two items in each case.^{25,26,24,25} Parent, sibling and peer smoking were assessed as factors from social environment (no vs. any parent/sibling/peer smoking). Finally, students were asked whether they had participated in a comprehensive prevention program in elementary school with examples of most broadly disseminated programs given.

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Procedure

In schools having agreed to participate, teachers of the respective 5th-~~five~~ grade collected the parental informed consent. Students with refusal were excluded from all assessments. Data assessment was conducted in the class room and lasted 45 minutes. Research staff was responsible for the distribution, help in completion and collection of the questionnaire. To permit a linking of individual baseline and follow-up data while assuring anonymity, students generated a seven digit individual code. This procedure has been tested and used in several studies and therefore been inspected and approved by Ethics Committee, data protection and Ministries of Education repeatedly.^{27,26} Teachers were not involved in ~~the~~ data assessment. At the end of the assessment, all questionnaires were placed in an envelope which was sealed in front of the class. Therefore, every student was assured that neither teachers nor parents were able to see the completed questionnaire.

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Ethical approval for the trial was gained from the Ethics Committee of Medical Faculty of the University of Kiel. Additional approvals (e.g., from ministries of education, and parents) were sought as required.

Analyses

Predictors of attrition were examined by multilevel mixed effect logistic regressions, ~~χ^2 and t-tests~~. To test for selective attrition, interaction effects for group condition and dependent variable were tested. Descriptive statistics (percentages, means, standard deviations) are crude values. To analyze ~~the~~ effects of the intervention on smoking behavior as well as on attitudes and knowledge, multilevel mixed effect regression models using Stata *mixed* and *meqrlogit* command were conducted, adjusting for covariates. In case of dichotomous outcomes, effect sizes (Cohen's d) were determined by using the converting formula

proposed by Borenstein et al.²⁸²⁷ Effect sizes for metric outcomes were calculated as proposed by Feingold.²⁹²⁸ All data analyses were conducted with Stata V.13.³⁰²⁹

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RESULTS

Attrition analysis

Among the 3,444 students assessed at baseline, there ~~was-were~~ no data available in the analysis sample for 931 students (27.0%). ~~Drop-out was higher in intervention group (N=506, 30.0%) compared to control group (N=425, 24.2%; $\chi^2(1)=15.02$, $p<0.001$).~~ Overall, significantly higher attrition was ~~also~~ found for male students (31.2%; $p<0.001$), ~~students attending other schools than Gymnasium (32.1%; $p<0.001$),~~ students with a migration background (36.5%; $p<0.001$), students indicating current smoking (45.7%; $p=0.004047$) or current use of alcohol (39.8%; $p<0.001$) at baseline. Furthermore, students dropping out of the study were older ~~than students in the retention sample~~ ($M_{\text{attrition}}=10.5$ vs. $M_{\text{retention}}=10.3$ years of age at baseline; $p<=0.001003$) ~~and had a lower SES ($M_{\text{attrition}}=-17.1$ vs. $M_{\text{retention}}=-17.9$; $p<0.001$) than students in the retention sample.~~ Besides these overall effects, no hints for selective attrition were found, i.e. the associations between variables listed above and attrition did not differ systematically between ~~the~~ intervention and control group.

Effects on smoking behavior

Students in ~~the~~ intervention and control group did not differ in rates for lifetime and current smoking at baseline. At follow-up, 16.0% of intervention students indicated that they had ever smoked in their lives compared to 20.2% in the control students (Figure 2). This difference was statistically significant also after controlling for confounding factors (adjusted Odds Ratio [OR]=0.63; 95% confidence interval [CI]=[0.41; 0.96]; $p=0.026$).

While about 1% of intervention and control students reported current smoking at baseline, these rates increased to more than 5% at follow-up both in intervention and control group.

Therefore, no group differences could be found in ~~the~~ frequency of current smoking.

At baseline, 95.6% of the sample were never-smokers (N=2,403; ~~I~~~~G~~intervention group: 96.4%, ~~G~~control group: 94.9%). Among these baseline never-smokers, 15.5% initiated smoking during the observation period. ~~The~~ incidence rate was significantly lower in intervention students, among whom 13.7% reported ~~the~~ first use of cigarettes between baseline and follow-up, compared to ~~the~~ control group with an incidence rate of 17.1% (adjusted OR=0.66, 95% CI=[0.43; 1.00], $p=0.047$).

- insert Figure 2 about here -

Effects on smoking related knowledge and attitudes

Students of both groups showed about the same level of smoking related knowledge at baseline with correct answering rates of about 30% (Table 1). At follow-up, students in both groups scored better in the knowledge test: intervention students had a mean percentage of correct answers of 46.75, while ~~the intervention-control~~ students rated on average 37.74% of the statements correctly. The increase in knowledge was significantly higher in ~~the~~ intervention ~~students-group~~ (adjusted $\beta=9.38$; 95% CI=[6.73; 12.04]; $p<0.001$).

- insert Table 1 about here -

A comparable pattern was found for attitudes towards smoking: At baseline, both groups did not differ in their attitudes and showed a rather critical perception of smoking with a mean score of 2.04 on the scale ranging from 0 to 3 (Table 1). At follow-up, students rated smoking even more negatively with a mean score of 2.24 in ~~the~~ intervention and 2.16 in ~~the~~ control group. Compared to ~~the~~ control group, this change in attitudes was more pronounced in ~~the~~ intervention group (adjusted $\beta=0.10$; 95% CI=[0.03; 0.16]; $p=0.002$).

Normative expectations were hardly influenced by the intervention: While intervention students estimated smoking prevalence in adults marginally lower at follow-up compared to their estimation at baseline, a small increase in this estimate could be observed in control students (Table 1). For peer smoking, both groups showed a small increase in perceived frequency of smoking. None of these changes turned out to be statistically significant after covariates and baseline estimates were controlled for.

Already at baseline, students in both groups considered themselves rather capable to refuse cigarette offers (Table 1). During ~~the~~ observation period, self-efficacy even grew with a slightly higher – but statistically insignificant – increase in intervention students compared to control students.

Table 1.
Descriptive statistics and multilevel mixed effects linear regressions for smoking related knowledge, attitudes, perceived norms and self-efficacy to refuse cigarette offers

	Baseline		Follow-up		Change		Difference in change		
	Beginning of grade 5		Mid of grade 7		Intervention	Control	adj. β^1	95% CI	p
	Intervention	Control	Intervention	Control					
	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)			
Knowledge ²	30.34 (19.47)	30.11 (19.14)	46.75 (21.59)	37.74 (20.45)	16.53 (26.46)	7.53 (24.13)	9.38	6.73; 12.04	<0.001
Attitudes/risk perception ³	2.04 (0.51)	2.04 (0.51)	2.24 (0.51)	2.16 (0.54)	0.20 (0.61)	0.12 (0.61)	0.10	0.03; 0.16	0.002
Norms adult smoking ⁴	6.08 (1.62)	5.97 (1.59)	6.04 (1.62)	6.09 (1.55)	-0.03 (2.09)	0.12 (1.95)	-0.08	-0.24; 0.07	0.265
Norms peer smoking ⁴	3.08 (2.64)	2.93 (2.56)	4.24 (2.28)	4.02 (2.18)	1.16 (3.10)	1.10 (2.93)	0.15	-0.13; 0.43	0.283
Self-efficacy to refuse cigarettes ⁵	2.38 (1.04)	2.36 (1.03)	2.53 (0.80)	2.49 (0.85)	0.15 (1.20)	0.11 (1.22)	0.07	-0.03; 0.17	0.140

M = Mean, SD = Standard deviation, CI = Confidence interval

¹ Adjusted for age, gender, type of school, socio-economic status, immigration background, peer / parent / sibling smoking, sensation seeking, rebelliousness, earlier participation in a prevention program, baseline value of the respective variable

² Mean percentage of correct answers in a 7-item quiz

³ Range 0 to 3, higher values representing more negative attitude

⁴ Range 0 = nobody smokes to 10 = everybody smokes

⁵ Range 0-3, higher values representing higher self-efficacy

Effect sizes for significant program effects were small to medium with $d=0.26$ (lifetime smoking), $d=0.23$ (incidence of smoking), $d=0.45$ (smoking related knowledge), and $d=0.15$ (attitudes/risk perception).

Sensitivity analyses

Since a substantial proportion of cases was excluded from the analysis sample due to inconsistent data ($N=180$) or as they were lost to follow-up ($N=931$), we conducted some sensitivity analyses to estimate the risk that the findings might be biased by these exclusions. First, we reran the analyses with inconsistent cases left in the dataset. This re-inclusion of inconsistent cases hardly changed the results for metric outcomes with significant effects for knowledge and attitudes and slightly changed results for smoking behavior with marginally significant associations for lifetime smoking ($p=0.086$) and incidence ($p=0.083$). To address the restriction of sample to complete cases, predictors for higher attrition were used as guide to create subsamples. As the attrition rate was highest in baseline current smokers and therefore this (small) subgroup of students smoking already very early might differ substantially from the majority of non-smoking students, we excluded baseline current smokers ($N=25$) completely. For this subsample, we found the same significant effects for lifetime smoking ($p=0.030$), knowledge ($p<0.001$) and attitudes ($p=0.002$) and no effects on current smoking, norms and self-efficacy. Further factors being associated with a higher risk of attrition (male gender, higher age, migration background) were explored by analyzing subsamples of male students, students aged ≥ 11 years at baseline and students with migration background. In these subsamples, incidence rates in control students exceeded those of intervention by 4 to 7 percent points (reaching significance for older students, $p=0.026$, marginal significance for students with migration background, $p=0.061$, and failing to reach significance for male students, $p=0.225$).

DISCUSSION

The current study aimed to investigate the effects of a school-based prevention program on smoking related knowledge, attitudes and behavior six months after the end of program implementation. Using a cluster randomized controlled design, findings revealed that the program participation seems to reduce the prevalence and incidence of lifetime smoking, to increase smoking related knowledge, and to influence attitudes and perceived risks of smoking towards a more critical perception. Program effects on the prevalence of current smoking, normative expectations or refusal skills could not be determined. Using Cohen's classification of effect sizes,³¹³⁰ effect size was small for smoking behavior and attitudes, while there was a medium effect on smoking related knowledge.

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The pattern found for effects on smoking behavior with significant small effects on smoking incidence ($d=0.23$) and lifetime smoking ($d=0.26$), and no effect on current smoking can be aligned quite well with [the](#) results presented in former meta-analyses: The pooled odds ratio of 0.88 for smoking onset at [the](#) longest follow-up revealed by the overall analysis of Thomas et al.^{13,42} corresponds to an effect size of $d=0.07$, while their subgroup analyses for different intervention approaches provided even moderate effect sizes (odds ratios between 0.49 and 0.52 corresponding to d 's between 0.36 and 0.39). Earlier meta-analyses on school-based drug prevention programs,^{14,43} psychosocial smoking prevention programs,^{15,44} or studies on Project DARE (Drug Abuse Resistance Education),^{16,45} the most widely used school-based drug prevention program in the United States and focusing on teaching skills to recognize and resist social pressure, also determined small program effects on substance use with d 's ranging between 0.08 and 0.18. Finding no effect on current smoking might also be explained to some extent by the young age of the sample with only very few students smoking already on a regular basis.

[The p](#)Participation in "Eigenständig werden 5+6" significantly increased smoking related knowledge with an effect size of $d=0.45$ – the highest effect found in our analyses. This medium effect is in line with effect sizes ranging from 0.36 to 0.42 determined in meta-analyses referred to above.^{14-16,43-45} Attitudes were influenced also significantly by the intervention, the small effect ($d=0.15$) compares well with [the](#) small effects in a range from 0.11 to 0.26 having been reported.^{14-16,43-45}

We were not able to show an effect of the intervention in correcting perceived norms of smoking or [in enhancing](#) self-efficacy to refuse offered cigarettes. Students of both intervention and control group consider themselves to be rather highly self-efficacious to resist to cigarette offers already at the outset of the study and this rating even increases in both groups at follow-up, i.e. a ceiling effect might decrease [the](#) discriminative power of the group comparisons. As far as perceived norms of smoking are concerned, a possible explanation of the null-effect is the fact that only a minor part of the intervention (one subtask among nine tasks of the smoking workshop at the end of grade 5) deals with the topic of norms. Most tasks in the workshop address facts about and visualization of [the](#) short- and long-term consequences of smoking, others aim to scrutinize strategies of [the](#) tobacco industry or to foster resistance skills.

Some limitations of the current study have to be considered: [During the 26 month period from baseline to follow-up, t](#)There has been some drop-out from the study, [from baseline to follow-up, t](#)he analysis sample ($N=2,513$) amounted to 73.0% of the baseline sample

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(N=3,444). This drop-out was slightly higher than expected in the a priori power calculation (25%), but since the baseline sample was somewhat larger than calculated (N=3,444 instead of N=3,160), the analysis sample still exceeds the estimated sample at follow-up (75% of 3,160 = 2,370). Therefore, the power of the analyses should be adequate.

~~Nevertheless~~Furthermore, we did not find any hints for selective attrition which could restrict the validity of findings and sensitivity analyses revealed very comparable patterns of results in subsamples with higher risk for attrition and smoking. The curriculum "Eigenständig werden 5+6" comprises of 14 lessons à on average 90 minutes and two workshops with 4 to 6 hours of duration which are implemented by teachers in addition to usual education, i.e. the program is quite time-consuming, it requires some dedication by teachers and it seems unreasonable to assume that the intervention is delivered to all classes exactly in the way and to the extent foreseen by the manual. ~~The a~~Analyses in this report were not controlled for treatment integrity, ^{32:3334:32} i.e. classes with low treatment fidelity ~~that and having have~~ only been exposed ~~only~~ to parts of the intervention contribute to the same extent to the results of the intervention group as classes with complete program implementation.

~~Therefore, and~~ results can be considered as rather conservative. Another limitation is the reliance on self-reports in the assessment of outcomes. Especially for outcomes assessing smoking behavior, but also for attitudes towards smoking, answers might be biased by social desirability. These influences might occur more likely in the intervention group since students might be primed by the intervention that smoking is an "unwanted" behavior. Nevertheless, since purchase of cigarettes and smoking in public is forbidden by law for minors in Germany, ~~also the~~ students in the control condition are not free of a social desirability bias as well. For other outcomes like the assessment of refusal skills, validity of self-report data might be limited by restricted accessibility, i.e. whether adolescents are really able to judge their own competence to resist cigarette offers. Finally, the study was run in regular public schools of four federal states of Germany, i.e. the generalizability might be limited due to these regional constraints and restricted to adolescents visiting regular schools.

On the other hand, some strengths of the current study ~~iesy~~ should be born in mind: Results were derived from a cluster randomized controlled trial, applying sophisticated statistical methods, comprising a range of several outcomes and following students up for six months after the end of intervention. Therefore, we implemented rather rigorous evaluation methods, which are in line with recommendations like those of the Society for Prevention Research, ^{34:33}

Perspectives and open questions for future research might be the following: In the current trial, a further follow-up at 15 months after end of intervention is being conducted to explore stability of effects in the longer term. Furthermore, exploring effects on other outcomes than

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smoking, e.g. alcohol use or life skills, is owing for the current study. On the basis of findings for efficacy, effectiveness in relation to costs as well as generalizability to other populations should be investigated. Finally, besides stating whether an intervention is effective or not, mechanisms by which shown effects can be explained theoretically and empirically are to be explored. These mediation analyses may contribute to investigate causal models for preventive intervention, e.g. to explore whether knowledge or change in attitude are necessary preconditions for behavior change.¹⁴⁴³

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Figure legends

Figure 1. Participation flowchart

Figure 2. Percentage of lifetime smoking, current smoking at baseline and 6-month follow-up, percentage of smoking incidence at 6-month follow-up among baseline never-smokers, and multilevel mixed effects logistic regressions; OR = odds ratio, CI = confidence interval; logistic regressions were adjusted for age, gender, type of school, socio-economic status, immigration background, peer / parent / sibling smoking, sensation seeking, rebelliousness, earlier participation in [a](#) prevention program

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Competing interests

None.

Ethics approval

Ethics approval was provided by the Ethics Committee of the Medical Faculty of the University of Kiel (Ref.: D 419/10).

Contributors

BI performed the statistical analysis and interpretation of the data and drafted the manuscript. JH contributed to the acquisition of the data and participated in drafting the manuscript. KM contributed to the acquisition and management of the data. RH as principle investigator is responsible for the study concept, design and supervision and helped in drafting the manuscript.

All authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors conducted a critical revision of the article and granted final approval of the article for important intellectual content.

Data sharing statement

No additional data available.

References

- (1) Lim SS, Vos T, Flaxman AD, Danaei G, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2013; 380(9859):2224-2260.
- (2) Bundeszentrale für gesundheitliche Aufklärung. Der Tabakkonsum Jugendlicher und junger Erwachsener in Deutschland 2012. Ergebnisse einer aktuellen Repräsentativbefragung und Trends. Köln: Bundeszentrale für gesundheitliche Aufklärung; 2013.
- (3) Robert Koch-Institut. Die Gesundheit von Kindern und Jugendlichen in Deutschland. Berlin: Robert Koch-Institut; 2013.
- (4) World Health Organisation. Life skills education in schools, parts 1 and 2. Geneva: WHO, Division of Mental Health; 1994.
- (5) Evans RI. Smoking in children: developing a social psychological strategy of deterrence. *Prev Med* 1976; 51:122-127.
- (6) Donaldson SI, Graham JW, Hansen WB. Testing the generalizability of intervening mechanism theories: understanding the effects of adolescent drug use prevention interventions. *J Behav Med* 1994; 17(2):195-216.
- (7) Flay BR. The promise of long-term effectiveness of school-based smoking prevention programs: a critical review of reviews. *Tob Induc Dis* 2009; 5(1):7.
- (8) Cuijpers P. Effective ingredients of school-based drug prevention programs. A systematic review. *Addict Behav* 2002; 27(6):1009-1023.
- (9) Gottfredson DC, Wilson DB. Characteristics of effective school-based substance abuse prevention. *Prev Sci* 2003; 4(1):27-38.
- (10) Flay BR. School-based smoking prevention programs with the promise of long-term effects. *Tob Induc Dis* 2009; 5(1):6.
- (11) Skara S, Sussman S. A review of 25 long-term adolescent tobacco and other drug use prevention program evaluations. *Prev Med* 2003; 37(5):451-474.
- (12) Wiehe SE, Garrison MM, Christakis DA, Ebel BE, Rivara FP. A systematic review of school-based smoking prevention trials with long-term follow-up. *J Adolesc Health* 2005; 36(3):162-169.
- (13) Thomas RE, McLellan J, Perera R. School-based programmes for preventing smoking. *Cochrane Database Syst Rev* 2013; 4:CD001293.
- (14) Tobler NS, Stratton HH. Effectiveness of school-based drug prevention programs: a meta-analysis of the research. *J Prim Prev* 1997; 18(1):71-128.

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(15) Hwang MS, Yeagley KL, Petosa R. A meta-analysis of adolescent psychosocial smoking prevention programs published between 1978 and 1997 in the United States. *Health Educ Behav* 2004; 31(6):702-719.

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(16) Ennett ST, Tobler NS, Ringwalt CL, Flewelling RL. How effective is drug abuse resistance education? A meta-analysis of Project DARE outcome evaluations. *Am J Public Health* 1994; 84(9):1394-1401.

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(17) Müller-Riemenschneider F, Rasch A, Bockelbrink A, Vauth C, Willich SN, Greiner W. Effectiveness and cost-effectiveness of behavioural strategies in the prevention of cigarette smoking. *GMS Health Technol Assess* 2008; 4:Doc10.

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(18) Cuijpers P. Three decades of drug prevention research. *Drug Educ Prev Polic* 2003; 10(1):7-20.

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(19) Hansen WB, Dusenbury L, Bishop D, Derzon JH. Substance abuse prevention program content: systematizing the classification of what programs target for change. *Health Educ Res* 2007; 22(3):351-360.

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(20) Hansen J, Hanewinkel R, Maruska K, Isensee B. The 'Eigenständig werden' prevention trial: a cluster randomised controlled study on a school-based life skills programme to prevent substance use onset. *BMJ Open* 2011; 1(2):e000352.

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(21) Gibbons FX, Gerrard M. Predicting young adults' health risk behavior. *J Pers Soc Psychol* 1995; 69(3):505-517.

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(22) Hawkins JD, Catalano RF, Miller JY. Risk and protective factors for alcohol and other drug problems in adolescence and early adulthood: implications for substance abuse prevention. *Psychol Bull* 1992; 112(1):64-105.

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(23) Petraitis J, Flay BR, Miller TQ. Reviewing theories of adolescent substance use: organizing pieces in the puzzle. *Psychol Bull* 1995; 117(1):67-86.

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(24) Currie C, Molcho M, Boyce W, Holstein B, Torsheim T, Richter M. Researching health inequalities in adolescents: the development of the Health Behaviour in School-Aged Children (HBSC) family affluence scale. *Soc Sci Med* 2008; 66(6):1429-1436.

Formatted: Font: Italic, Do not check spelling or grammar

(25) Stephenson MT, Hoyle RH, Palmgreen P, Slater MD. Brief measures of sensation seeking for screening and large-scale surveys. *Drug Alcohol Depend* 2003; 72(3):279-286.

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(26) Burt RD, Dinh KT, Peterson Jr AV, Sarason IG. Predicting adolescent smoking: a prospective study of personality variables. *Prev Med* 2000; 30(2):115-125.

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(27) Galanti MR, Siliquini R, Cuomo L, Melero JC, Panella M, Faggiano F. Testing anonymous link procedures for follow-up of adolescents in a school-based trial: The EU-DAP pilot study. *Prev Med* 2007; 44(2):174-177.

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(28) Borenstein M, Hedges LV, Higgins JPT, Rothstein HR. Introduction to meta-analysis. Chichester: Jon Wiley & Sons; 2009.

(29) Feingold A. Effect sizes for growth-modeling analysis for controlled clinical trials in the same metric as for classical analysis. *Psychol Methods* 2009; 14(1):43-53.

Formatted: Font: Italic, Do not check spelling or grammar

(30) StataCorp. Stata Statistical Software: Release 13. College Stations, Texas: StataCorp; 2013.

- (31) Cohen J. Statistical power analyses for behavioral science. Hilldale, New York: Erlbaum; 1988.
- (32) Bishop DC, Pankratz MM, Hansen WB, Albritton J, Albritton L, Strack J. Measuring Fidelity and Adaptation: Reliability of a Instrument for School-Based Prevention Programs. *Eval Health Prof* 2013.
- (33) Dusenbury L, Brannigan R, Falco M, Hansen WB. A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Educ Res* 2003; 18(2):237-256.
- (34) Flay BR, Biglan A, Boruch RF, Castro FG, Gottfredson D, Kellam S et al. Standards of evidence: criteria for efficacy, effectiveness and dissemination. *Prev Sci* 2005; 6(3):151-175.

REFERENCES

- (1) ~~Lim SS, Vos T, Flaxman AD, Danaei G, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2013; 380(9859):2224-2260.~~
- (2) ~~Bundeszentrale für gesundheitliche Aufklärung. Der Tabakkonsum Jugendlicher und junger Erwachsener in Deutschland 2012. Ergebnisse einer aktuellen Repräsentativbefragung und Trends. Köln: Bundeszentrale für gesundheitliche Aufklärung; 2013.~~
- (3) ~~World Health Organisation. Life skills education in schools, parts 1 and 2. Geneva: WHO, Division of Mental Health; 1994.~~
- (4) ~~Evans RI. Smoking in children: developing a social psychological strategy of deterrence. *Prev Med* 1976; 5(1):122-127.~~
- (5) ~~Donaldson SI, Graham JW, Hansen WB. Testing the generalizability of intervening mechanism theories: understanding the effects of adolescent drug use prevention interventions. *J Behav Med* 1994; 17(2):195-216.~~
- (6) ~~Flay BR. The promise of long term effectiveness of school based smoking prevention programs: a critical review of reviews. *Tob Induc Dis* 2009; 5(1):7.~~
- (7) ~~Cuijpers P. Effective ingredients of school based drug prevention programs. A systematic review. *Addict Behav* 2002; 27(6):1009-1023.~~
- (8) ~~Gottfredson DC, Wilson DB. Characteristics of effective school based substance abuse prevention. *Prev Sci* 2003; 4(1):27-38.~~
- (9) ~~Flay BR. School based smoking prevention programs with the promise of long term effects. *Tob Induc Dis* 2009; 5(1):6.~~
- (10) ~~Skara S, Sussman S. A review of 25 long term adolescent tobacco and other drug use prevention program evaluations. *Prev Med* 2003; 37(5):451-474.~~

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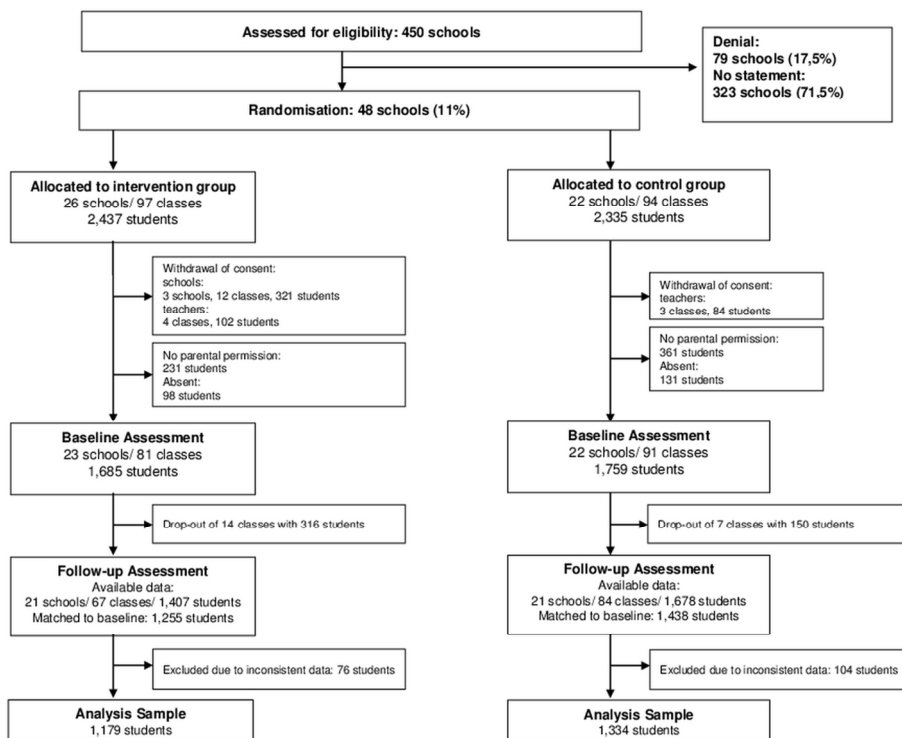
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- ~~(11) Wiehe SE, Garrison MM, Christakis DA, Ebel BE, Rivara FP. A systematic review of school-based smoking prevention trials with long-term follow-up. *J Adolesc Health* 2005; 36(3):162-169.~~
 - ~~(12) Thomas RE, McLellan J, Perera R. School-based programmes for preventing smoking. *Cochrane Database Syst Rev* 2013; 4:CD001293.~~
 - ~~(13) Tobler NS, Stratton HH. Effectiveness of school-based drug prevention programs: a meta-analysis of the research. *J Prim Prev* 1997; 18(1):71-128.~~
 - ~~(14) Hwang MS, Yeagley KL, Petosa R. A meta-analysis of adolescent psychosocial smoking prevention programs published between 1978 and 1997 in the United States. *Health Educ Behav* 2004; 31(6):702-719.~~
 - ~~(15) Ennett ST, Tobler NS, Ringwalt CL, Flewelling RL. How effective is drug abuse resistance education? A meta-analysis of Project DARE outcome evaluations. *Am J Public Health* 1994; 84(9):1394-1401.~~
 - ~~(16) Müller-Riemenschneider F, Rasch A, Bockelbrink A, Vauth C, Willich SN, Greiner W. Effectiveness and cost-effectiveness of behavioural strategies in the prevention of cigarette smoking. *GMS Health Technol Assess* 2008; 4:Doc10.~~
 - ~~(17) Cuijpers P. Three decades of drug prevention research. *Drug Educ Prev Polic* 2003; 10(1):7-20.~~
 - ~~(18) Hansen WB, Dusenbury L, Bishop D, Derzon JH. Substance abuse prevention program content: systematizing the classification of what programs target for change. *Health Educ Res* 2007; 22(3):351-360.~~
 - ~~(19) Hansen J, Hanewinkel R, Maruska K, Isensee B. The 'Eigenständig werden' prevention trial: a cluster randomised controlled study on a school-based life skills programme to prevent substance use onset. *BMJ Open* 2011; 1(2):e000352.~~
 - ~~(20) Gibbons FX, Gerrard M. Predicting young adults' health risk behavior. *J Pers Soc Psychol* 1995; 69(3):505-517.~~
 - ~~(21) Hawkins JD, Catalano RF, Miller JY. Risk and protective factors for alcohol and other drug problems in adolescence and early adulthood: implications for substance abuse prevention. *Psychol Bull* 1992; 112(1):64-105.~~
 - ~~(22) Petraitis J, Flay BR, Miller TQ. Reviewing theories of adolescent substance use: organizing pieces in the puzzle. *Psychol Bull* 1995; 117(1):67-86.~~
 - ~~(23) Currie C, Molcho M, Boyce W, Holstein B, Torsheim T, Richter M. Researching health inequalities in adolescents: the development of the Health Behaviour in School-Aged Children (HBSC) family affluence scale. *Soc Sci Med* 2008; 66(6):1429-1436.~~
 - ~~(24) Stephenson MT, Hoyle RH, Palmgreen P, Slater MD. Brief measures of sensation seeking for screening and large scale surveys. *Drug Alcohol Depend* 2003; 72(3):279-286.~~
 - ~~(25) Burt RD, Dinh KT, Peterson Jr AV, Sarason IG. Predicting adolescent smoking: a prospective study of personality variables. *Prev Med* 2000; 30(2):115-125.~~

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- ~~-(26) Galanti MR, Siliquini R, Cuomo L, Melero JC, Panella M, Faggiano F. Testing anonymous link procedures for follow up of adolescents in a school-based trial: The EU-DAP pilot study. *Prev Med* 2007; 44(2):174-177.~~
- ~~-(27) Borenstein M, Hedges LV, Higgins JPT, Rothstein HR. Introduction to meta-analysis. Chichester: Jon Wiley & Sons; 2009.~~
- ~~-(28) Feingold A. Effect sizes for growth modeling analysis for controlled clinical trials in the same metric as for classical analysis. *Psychol Methods* 2009; 14(1):43-53.~~
- ~~-(29) StataCorp. Stata Statistical Software: Release 13. College Stations, Texas: StataCorp; 2013.~~
- ~~-(30) Cohen J. Statistical power analyses for behavioral science. Hilldale, New York: Erlbaum; 1988.~~
- ~~-(31) Bishop DC, Pankratz MM, Hansen WB, Albritton J, Albritton L, Strack J. Measuring Fidelity and Adaptation: Reliability of a Instrument for School Based Prevention Programs. *Eval Health Prof* 2013.~~
- ~~-(32) Dusenbury L, Brannigan R, Falco M, Hansen WB. A review of research on fidelity of implementation: implications for drug abuse prevention in school settings. *Health Educ Res* 2003; 18(2):237-256.~~
- ~~-(33) Flay BR, Biglan A, Boruch RF, Castro FG, Gottfredson D, Kellam S et al. Standards of evidence: criteria for efficacy, effectiveness and dissemination. *Prev Sci* 2005; 6(3):151-175.~~

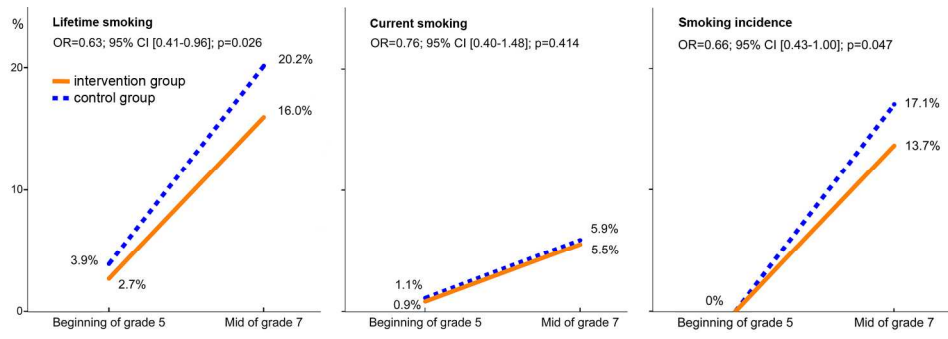


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Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	p. 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	p. 2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	p. 5
	2b	Specific objectives or hypotheses	Whether objectives pertain to the cluster level, the individual participant level or both	p. 5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	p. 6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		p. 6
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	p. 6
	4b	Settings and locations where the data were collected		p. 6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	p. 5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	p. 7

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		n.a.
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or <i>k</i>), and an indication of its uncertainty	p. 6
	7b	When applicable, explanation of any interim analyses and stopping guidelines		n.a.
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		p. 6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	p. 6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	p. 6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	p. 6
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	p. 6

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	p. 8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		n.a.
	11b	If relevant, description of the similarity of interventions		n.a.
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	p. 9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		p. 9
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	p. 6 Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	p.6
Recruitment	14a	Dates defining the periods of recruitment and follow-up		p. 6
	14b	Why the trial ended or was stopped		n.a.
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	p. 6
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	p. 9-
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		p. 9-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		p. 9-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		p. 13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	p. 13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		p. 12-
Other information				
Registration	23	Registration number and		p. 2

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	p. 6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p. 15

* Note: page numbers optional depending on journal requirements

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