The „Eigenständig werden" prevention trial: a cluster randomised controlled study on a school-based life skills programme to prevent substance use onset.

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2011-000352
Article Type:	Research
Date Submitted by the Author:	26-Aug-2011
Complete List of Authors:	Hansen, Julia; Institute for Therapy and Health Research, IFT-Nord Hanewinkel, Reiner; Institute for Therapy and Health Research, IFT-Nord Maruska, Karin; Institute for Therapy and Health Research, IFT-Nord Isensee, Barbara; Institute for Therapy and Health Research, IFT-Nord
Primary Subject Heading:	Public health
Keywords:	School-based prevention programme, general life skills, substance use

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Study protocol and baseline characteristics

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Key words

School-based prevention programme, life skills, substance use

Word count

3815

ABSTRACT

Background

The aim of this study is the implementation and evaluation of “Eigenständig werden 5+6” (“Becoming Independent 5+6”), a school-based curriculum for grade 5 and 6 developed upon evidence-based criteria for effective drug prevention curricula in schools. Evaluation of the programme includes efficacy, feasibility, and practicability in daily school routine.

Methods and analysis

The intervention “Eigenständig werden 5+6” consists of 14 teaching units evenly distributed over grades five and six which are interactively delivered, and a parent component. Programme effects are studied in a four wave cluster randomised controlled trial with two arms, an intervention and a control condition. Self-completed questionnaires from students and teachers are collected by trained research staff.

45 schools, 172 classes and 3,444 students with a mean age of 10.37 years (SD=.59) and 47.9% girls from four federal states in Germany were assessed at baseline. 1,685 students in 81 classes were assigned to intervention classes, 1,759 students in 91 classes to control arm.

No differences between conditions were either found for age, gender, immigration background, socio-economic status, substance use, or life skills at baseline. Exceptions are higher self-efficacy ($t_{(3438)}$=2.34, p=.02, d=.08) and empathy ($t_{(3302)}$=2.4, p=.02, d=.09) reported for control group whereas class climate seems better in intervention condition ($t_{(3037)}$=2.01, p=.05, d=.07), but effect sizes state marginal differences.

Ethics and dissemination

Ethical approval was granted by the Ethics Committee of the Medical Faculty of the University of Kiel. The study was approved by respective Ministries of Education.

Conclusion

Baseline data suggest that the initial conditions are favourable for testing programme efficacy since distribution of baseline levels of the outcomes does not differ in intervention and control condition, except negligible differences between self-efficacy and empathy higher in the control group and class climate higher in the intervention group.

Trial registration: Current Controlled Trials ISRCTN99442407

ARTICLE SUMMARY

Article focus

- The focus of this study is to implement and evaluate a school-based curriculum for students in grade five and six, developed upon evidence-based criteria for effective drug prevention curricula in schools.
- It is hypothesised that the intervention will lead to an increase of general life skills, refusal skills, and knowledge about substance use. These enhancements should be accompanied by a lower likelihood of smoking onset and alcohol consumption.

Key messages

- Due to inconsistent results concerning long-term effects and effective programme components of school-based prevention programmes, there is a need for further research in this field. This trial addresses this need.

Strengths and limitations

Strengths:

- This cluster randomised controlled trial includes a large sample of adolescents.
- A wide spectrum of outcomes and confounders will be assessed in four waves including not only post-test but also follow-up.

Limitations:

- Self-reports of students may be a limiting factor to this study.

BACKGROUND

Introduction

Albeit lifetime smoking prevalence at the age between 12 and 17 years has declined in Germany over the last decade [1], substance abuse is still one of the major threats to adolescent's health in Germany and Western cultures in general [2,3]. In particular, tobacco smoking and alcohol consumption are serious problems not only for adolescent but also for adulthood health considering that juvenile behavioural pattern such as smoking will presumably establish itself in adulthood, since the majority of adult smokers report having started at an early age [4-6]. Especially adolescents aged between 12 and 14 years represent the high risk group for an onset of alcohol consumption and smoking initiation. Preventing juvenile substance use is therefore an important aim to avoid premature mortality and morbidity and to pave the way for a healthy lifestyle.

School-based prevention programs are considered to be one of the most appropriate and suitable strategies to tackle substance use [7-9]. Informational programs seem not as effective as those that focus on psychosocial strategies and educate adolescents about social norms and influences [10]. Another promising approach to promote a healthy lifestyle is the development and improvement of general life skills [11], skills for resisting social influence and substance-specific skills in adolescence [12]. General life skills empower adolescents in challenging situations, help to master life as competent as possible as well as to deal effectively with the realities of life, and help to prevent substance use and addiction. Enabling children to acquire knowledge and developing attitudes and life skills which support the adoption of healthy behaviours is an approach strongly recommended by the World Health Organization (WHO) [13]. For this reason, some primary prevention programs are based on the life skills approach even though the empirical evidence of the efficacy of these programs is rather weak [14]. Research on effective program components as well as on long-term effects have shown inconsistent results [7,15,16] and further research is needed.

Aims and hypotheses

The focus of this study is to implement and evaluate a school-based curriculum for students in grade five and six, developed upon evidence-based criteria for effective drug prevention curricula in schools. The overall aim of this school-based curriculum is the prevention of substance use and addiction by increasing substance specific skills and general life skills of students in grade five and six. To evaluate effects as well as feasibility and practicability of the program, a four-wave controlled study is conducted in daily school routine.

“Eigenständig werden 5+6” (“Becoming independent 5+6”) is a universal school-based prevention program for grade five and six based on the social influence model and on the life skills approach. It contains substance-specific as well as substance-unspecific elements and takes quality criteria of effective prevention programs into account [8,17-19]. It is expected that participation in the prevention program will lead to lower rates of adolescent’s smoking initiation and to abstinence from alcohol or at least to a more responsible consumption. The program is designed to address both the social and psychological factors promoting the onset of tobacco smoking and drinking alcohol by attempting to increase the students' ability to cope with pressures to smoke and to drink and to decrease student’s susceptibility to pro-smoking and pro-alcohol social influences. It targets at the improvement of students’ refusal skills and their ability to cope with emotions, stress and problems. Overall, dependent variables to be influenced by the prevention program are use of tobacco and alcohol, smoking-related and alcohol-related knowledge, intentions and attitudes towards substance use, susceptibility to smoking cigarettes and alcohol and general life skills, social skills as well as substance-specific refusal skills.

METHODS AND ANALYSIS

Intervention

”Eigenständig werden 5+6” was designed by an interdisciplinary team of psychologists, sports scientists and pedagogues. The prevention program consists of twelve 45- to 90-

minute units. The units are evenly distributed over grades five and six and include the following components: life skills (i.e. problem solving, critical thinking, effective communication skills, decision-making, interpersonal relationship skills, self-awareness building skills, empathy, coping with stress, and emotions), student's ability to work in a group and substance specific skills. To facilitate the accomplishment of the prevention program, an order of units was predetermined.

In addition, alcohol and smoking are addressed in two workshops lasting four till six hours. The workshops include several activities about substance use such as smoking cigarettes and alcohol abuse, and will be carried out at the end of grade five and six. Profound knowledge and skills will be conveyed in these workshops by providing different learning stations for students. Students can choose in what order they do the stations but are required to complete all of them. At the end of grade five, tobacco smoking is the general topic whereas alcohol consumption will be addressed at the end of grade six.

The entire prevention program is conducted by the teachers in classroom during usual school lessons. Teachers receive a manual which provides specific instructions and background information that is needed to conduct the units and they took part in a two day training course that was carried out by especially qualified prevention experts. To develop life skills, miscellaneous teaching methods, such as interactive didactics, working in small groups, relaxation exercises, pantomime, identification figures, and active games are used. Units as well as workshops include working sheets and several background information and instructions.

Additionally, the program involves parents by providing three parent-teacher conferences and different informational material to keep them informed on their children's subjects. The informational materials include suggestions and rules on how to support their children. To take families with an immigration background into consideration, all parental information are also available in Turkish and Russian.

Study Design

To evaluate effects of “Eigenständig werden 5+6”, a four-wave cluster randomised controlled trial with two arms, an intervention and a control condition, is conducted. The intervention group takes part in the prevention programme and will be compared with the non-treated, “usual curriculum” control group. The actual intervention duration is from the beginning in grade five (October/November 2010) till the end of grade six, spanning a period of two school years. The randomisation occurred at school level to avoid information exchange between the conditions in the schools. Data are collected prior to the start of the intervention (September/October 2010), at the end of grade five (June/July 2011), at the end of grade six (June/July 2012) and in the middle of grade seven (December 2012).

Calculated sample size

The cluster randomised trial involves randomising social units or clusters of individuals rather than individuals themselves. Specific constraints must be considered during planning and analysis [20]. Indeed, the responses of individuals within a cluster tend to be more similar than those of individuals of different clusters. The clustering effect is defined as $1 + (m - 1)p$, where m is the average number of subjects per cluster and p the intraclass correlation coefficient (ICC) [21]. Values of ICC for smoking and drinking behaviour were taken from the EU Drug Addiction Prevention Trial [22], and were estimated with approximately 0.02, which is in line with other estimations [23].

Power calculations were run with a sample size calculator for cluster randomized trials [24]. Based on earlier experiences, a drop-out rate of 25% was hypothesized. Taking as current estimates, the lifetime smoking prevalence at the age between 12 and 17 years (at the time of the follow-up tests the age of most students will be approximately 13 till 14 years) was valued with 43% [25], whereas the lifetime prevalence of alcohol consumption at the age between 11 and 17 years was estimated with 64% [26].

Applying a significance level of alpha=0.05, power=0.80, a 15% prevention effect, and an average number of 20 students per class (*m*), the power calculations resulted in a recommended sample size of 158 classes and 3,160 students.

Sample recruitment

Sample recruitment took place in four German federal states: Schleswig-Holstein, North-Rhine-Westphalia, Hesse and Bremen. In order to achieve a balanced representation of social strata, complete lists of all secondary schools (except schools with students for special needs) of selected regions in Schleswig-Holstein, North-Rhine-Westphalia, and Hesse were obtained from the Ministries of Education of each federal state. In Bremen, all secondary schools were included. Invited school types range from *Gymnasium* which is defined as a school for students who have high academic skills and aim for university-entrance diploma after accomplishment, to *Realschule*, *Hauptschule* and *Regionalschule* that focus on students with lower academic skills compared to *Gymnasium*. After attending elementary school, *Gymnasium* requires 8 till 9 years of school whereas students of *Realschule*, *Hauptschule* or *Regionalschule* need to attend school for 5 till 6 years. Other school types included are *Gemeinschaftsschule* as well as *Gesamtschule* which offer all kind of degrees and in which students with varying academic skills are taught together.

Invitation letters and information sheets explaining the aims of the study were sent to the head teachers of 450 secondary schools in the study regions. Schools were invited to participate in the trial with all classes in grade five and were sent a detailed memorandum of understanding to sign and to obtain head teachers' written commitment to the trial. The importance of the randomized design was emphasized and it was made clear to schools that it would be preferable for them to decline participation rather than to join the study and withdraw commitment at a later point. Schools agreeing to participate registered for the study by indicating general interest and the number of fifth grade classes interested in the study, the names of the class teachers and the number of students per class. In addition, schools could ask for visits of the project staff to receive first hand information on the requirements of the trial.

323 out of 450 schools invited did neither express approval nor disapproval, whereas 79 schools with approximately 180 fifth grade classes denied their participation mostly due to shortage of time because of structural changes imposed by Ministries of Education. 48 schools (11%) with 191 classes and 4,772 students out of 450 schools invited decided to take part in the study. The highest rate of participation was found for Hesse as 28% of all schools invited decided to join the study. A lower rate can be stated for North-Rhine-Westphalia (15%) and Bremen (14%) as well as for Schleswig-Holstein (8%) where only 18 out of 228 schools agreed to participate.

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. Of these 48 schools agreeing to participate, 26 schools with 97 classes and 2,437 students were allocated to intervention group whereas 22 schools with 94 classes and 2,335 students were assigned to control condition. After randomisation, three schools of intervention group withdrew their consent as well as four teachers of intervention classes refused to take part. Taking absent students and those with no parental permission into account, baseline data of 23 intervention schools with 81 classes and 1,685 students were available.

In control condition, teachers of three classes withdrew consent, 361 students had no parental permission and 131 were absent at day of data collection. Therefore, baseline data of 22 schools with 91 classes and 1,759 students were collected (see Figure 1).

Thus, 45 schools and 172 classes take part in the study and data of 3,444 students were assessed at baseline altogether. An overall of 592 students were not eligible because of missing parental consent. Considering the recommended sample size, the sample of 172 classes with 3,444 students at baseline fits the results of the power analysis (158 classes with 3,160 students needed).

Questionnaire

Data was collected through self-completed anonymous questionnaires by teachers and students at baseline, prior to the beginning of the intervention and will be assessed by the same method in further waves.

Questionnaire (students)

The students' questionnaire was developed and designed, pretested and modified prior to the baseline assessment.

At the beginning of the development of the questionnaire, a focus group of students (N=7) was interviewed to gain insight into student's environment to detect, for example, typical situations that might be stressful or that cause problems for this age group. This information helped to develop a questionnaire that is appropriate for students in grades five and six. Afterwards, a first version of the questionnaire was pretested in four fifth grade classes (N=95) and additionally in two classes (N=14) in schools for children with special needs to eliminate items hard to understand as well as items with poor psychometric quality.

The final questionnaire assesses outcomes such as use of tobacco and alcohol consumption in forms of current behaviour and lifetime prevalence, smoking-related and alcohol-related knowledge, intentions and attitudes towards substance use, susceptibility to smoking cigarettes and alcohol and general life skills, social skills and substance-specific refusal skills. Questions concerning substance use covered own lifetime smoking prevalence likewise alcohol consumption. Furthermore, frequency of current consumption, episodes of drunkenness and binge drinking were investigated. Knowledge, intentions and attitudes about smoking cigarettes and drinking alcohol, susceptibility along with smoking and alcohol related behaviour of peers and family were included. Confounders like socio-demographic characteristics, bullying, class climate and leisure time behaviour were also assessed at baseline, stable traits like characteristics of personality and general parenting style will be assessed at post-test, due to aspects of feasibility (especially length of questionnaire and time needed for completion).

In general, items included in the questionnaire are based on “standard” questions used in the international literature, in published questionnaires or in own previous research. Table 1 summarizes all variables including references.

Table 1. Overview of variable constructs.

General life skills	Substance use (Smoking and alcohol)	Additional/Confounders
Communication [27,28]	Smoking-related and alcohol-related knowledge	Socio demographic characteristics [29]
Self esteem [30]	Use of tobacco [31,32]	General parenting style* [33]
Self-efficacy [28]	Use of alcohol [35]	Personality characteristics* [36,37]
Self concept [27]	Intentions and attitudes and normative expectations [38]	Leisure time behaviour [34]
Empathy [39]	Susceptibility [40]	Class climate**
Emotions [41]	Resistance skills [42]	Bullying [43,44]
Stress [45]	Social influence [32,46]	
Problem solving [27]	Perceived parental rules and attitudes [47,48]	

* Assessed at first post-test. ** On the basis of own previous research.

Specific values for the life skills-scales, for intentions, attitudes and perceived risks at baseline along with representative items and used response scales are displayed in table 2. If item-total correlation, difficulty or Cronbach’s Alpha exceed limiting values, scales were modified for data analysis by excluding items in order to increase psychometric quality. All values shown in table 2 represent final scales. Stress, problem-solving, and handling emotions will be interpreted on single item level in order to ascertain student’s strategies to handle situations and to cluster specific types.

Table 2. Internal consistency at baseline.

Scales (Item exemplification)	Cronbach's α	Number of Items	Item-total Correlation r_{it}	Item Difficulty P_i in %
Communication *("If I talk to somebody, I will not interrupt him/her")* *Response category: 4 point scale (I do not agree – I agree)*	α =.73	9	.35 - .48	57 - 86
Self esteem *("I sometimes think that I'm no good")* *Response category: 4 point scale (I do not agree – I agree)*	α =.70	5	.25 - .60	60 - 85
Self-efficacy *("Whatever happens, I will handle it")* *Response category: 4 point scale (I do not agree – I agree)*	α =.61	5	.26 - .41	58 - 70
Self concept *("I"m aware of my strengths")* *Response category: 4 point scale (I do not agree – I agree)*	α =.67	8	.27 - .42	55 - 82
Class climate *("We help each other")* *Response category: 4 point scale (I do not agree – I agree)*	α =.73	9	.35 - .48	57 - 86
Bullying *("How often have you taken part in bullying (kicking, beating) another student?")* *Response category: 5 point scale* *(Never - Few times a week)*	α =.71	3	.51 - .57	5 - 13
Victimization *("How often have you been bullied (kicking, beating) by another student?")* *Response category: 5 point scale* *(Never - Few times a week)*	α =.78	3	.57 - .67	14 - 22
Smoking-related perceived risks *("I will be sick")* *Response category: 4 point scale (Surely not - Surely yes)*	α =.76	6	.43 - .58	60 - 78
Alcohol-related perceived risks *("I will be sick")* *Response category: 4 point scale (Surely not - Surely yes)*	α =.79	5	.53 - .61	63 - 80

Questionnaire (teachers)

Teachers were asked to complete a questionnaire to assess class climate. They should evaluate working atmosphere including student's ability to work together, concentration, motivation, and pace of work, student's ability to solve problems, the corporate feeling of the class as well as the relationship between students and teachers by assigning marks from 1 (very good) up to 6 (very poor). Cronbach's Alpha of class climate scale is acceptable (α=.86, r_{it}≥.41).

Process evaluation

Teachers of the intervention group will additionally evaluate the implementation of the intervention programme and feasibility of every unit they will conduct. They were instructed while attending the teacher training and received questionnaires to document the process of implementation of "Eigenständig werden 5+6". These questionnaires cover the following information: date and duration of implementation, number of students attending the class, whether each of the core activities was or was not implemented, and a final judgment of the unit. By leaving space for open commentaries, teachers were encouraged to report their opinion on the units and activities as well as for anything else they want to comment. Furthermore, they should appraise the units' age-appropriateness and contents, and students' participation in the units.

Assessment procedure

The assessment was planned by asking schools about their preferred date and time for data collection at the beginning of grade five. Contemporaneously, teachers collected the parental permission of all students in class. In three regions, passive parental permission was used, i.e. parents had to refuse to take part in the study rather than to agree. In one region, an active permission was requested by the respective Ministry, i.e. parents had to agree in case they complied with participation. Teachers registered all names of students with no permission in a list which should be saved in the schools throughout the entire trial. All students with refusal are excluded from all assessments. To permit a linking of individual

information on subsequent surveys while assuring anonymity, each questionnaire is labelled with a seven-digit individual code generated by the student. 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 [49].

Data assessment was conducted in the class room and lasted 45 minutes. Project staff was responsible for the distribution, help in completion and collection of the questionnaire. Teachers were not involved. At the end of the assessment, all questionnaires which were completely filled out were placed in an envelope and sealed in front of the class. Every student was therefore assured that neither teachers nor parents were able to see the completed questionnaire.

79% (2,719) of all students were able to complete the questionnaire in 45 minutes. Students, who were not able to complete the entire questionnaire in 45 minutes, received a prepaid envelope. While the completed pages were collected by the staff, the students marked their own individual code on the last page, completed the unfilled pages of the questionnaire and anonymously sent it back to the project team. 46 % (331) of the students sent the pages back. Taking the questionnaires of absent students as well as afterwards sent pages into account, an overall of 2,922 data sets is complete at baseline. 522 data sets contain missing values on at least one page. Absent students were given a questionnaire and instructions in a prepaid envelope. After completion, they sent it back to the project team. An overall of 180 questionnaires were left in schools for absent students. 95 of these questionnaires (53%) were sent back completely filled out.

Baseline characteristics

A total number of 45 schools, 172 classes and 3,444 students with a mean age of 10.37 years (SD=.59) and 47.9% girls from four federal states in Germany were assessed at baseline. Baseline data suggest that the initial conditions are favourable for testing programme efficacy, since distribution of baseline levels of the outcomes does not differ in intervention and control condition. Exceptions are higher self-efficacy ($t_{(3438)}$=2.34, p=.02,

d=.08) and empathy ($t_{(3302)}$=2.4, p=.01, d=.09) reported for control students, whereas class climate, rated by students, seems better in intervention condition ($t_{(3037)=}$2.01, p=.05, d=.07), but effect sizes state marginal differences. Different distribution between the intervention and the control arm at baseline assessment was also found for school type with a higher proportion of students of *Gymnasiums* in control condition ($X^2_{(1)}$=17.7, p=.001). Differences between the intervention and control condition were neither found for age, gender, immigration background nor socio-economic status. Likewise, no significant differences between intervention and control condition were found for teacher's evaluation of class climate.

Table 3 shows the characteristics of the baseline survey for intervention and control condition and displays test statistics of differences between the conditions. Since responses of students within their classes tend to be more similar than those of students of other classes, the intra-class correlation coefficients for substance use are displayed as well.

Table 3. Characteristics at the baseline survey.

Baseline characteristics		Group				Difference
		Intervention (n=1,685)		Control (n=1,759)		
		N/ M (SD)	%	N/ M (SD)	%	
Gender	Boys	866	51.5	926	52.8	$X^2_{(1)}$=0.51, p=.48
	Girls	816	48.5	831	47.3	
Age		10.38 (.60)		10.35 (.58)		$t_{(3433)}$=1.27, p=.21
School type	Gymnasium	620	36.8	771	43.7	$X^2_{(1)}$=17.7, p=.001
	Others	1,065	63.2	988	56.3	
	Yes	372	22.3	409	23.3	
Socio-economic status*		4.44 (1.10)		4.44 (1.08)		$t_{(3439)}$=0.01, p=.99
Lifetime smoking	None	1,575	94.4	1,629	93.6	$X^2_{(4)}$=2.6, p=.63 ICC_{Cl}=.02 ICC_{Sch}=.03
	Only a few puffs	51	3.1	63	3.6	
	1 -19 cigarettes	37	2.2	40	2.3	
	20-100 cigarettes	5	.30	5	.29	
	> 100 cigarettes	1	.06	4	.23	
Current smoking	No	1,657	98.8	1,724	98.6	$X^2_{(4)}$=1.5, p=.83 ICC_{Cl}=.01 ICC_{Sch}=.01
	Yes	21	1.2	25	1.4	
Lifetime alcohol consumption	No	1,089	65.3	1,107	63.6	$X^2_{(2)}$=1.8, p=.40 ICC_{Cl}=.05 ICC_{Sch}=.02
	Yes	576	34.5	631	36.3	
Lifetime alcohol consumption without parent's knowledge	No	1,603	96.0	1,673	96.1	$X^2_{(1)}$=1.02, p=.60 ICC_{Cl}=.09 ICC_{Sch}=.02
	Yes	64	4.0	67	3.9	
Current alcohol consumption ("in the last 30 days")	Never	1,572	94.1	1,642	94.4	$X^2_{(2)}$=1.6, p=.44 ICC_{Cl}=.01 ICC_{Sch}=.004
	On 1-2 days a month	85	5.1	77	4.4	
	≥3 days a month	14	0.8	20	1.2	

*Socio-economic status was measured by Family Affluence Scale [29]; sum of two items: (range from 0 up to 3, a higher mean represents a higher socio-economic status). Abbreviation: Cl=classes, Sch=scho

Statistical analysis

To test efficacy of the programme and to give consideration to cluster effects, state of the art analyses in this field including multilevel modelling will be carried out. In order to test effective programme components mediation analysis will be performed.

In a first step, it can be analysed if the lessons of prevention programme have affected what they ought to affect: Students of the intervention group should have higher substance-specific competencies and also higher substance-unspecific skills. In a second step, it can be analysed if a given change in substance use (=dependent variable) in the intervention group is mediated by (1) the substance-specific skills, (2) the substance-unspecific skills, (3) by both, or (4) by neither nor.

ETHICS AND DISSEMINATION

Prior to the evaluation, the trial was approved and registered by the ethics committee of the Medical Faculty of the University of Kiel (AZ D 419/10) and approved by Ministries of Education. Parents were fully informed about the trial and its aim. Depending on the federal state, parental consent had to be given either in form of an active agreement or in form of a passive agreement. Students with no parental consent are excluded from all assessments. Anonymity is assured by using a seven-digit individual code that is generated by each student. The assessments are optional and each student can deny completing the questionnaire without any explanation.

CONCLUSION

The aim of the “Eigenständig werden 5+6” trial is to evaluate the efficacy of a school-based prevention program for substance use. It involves more than 3,000 students from four federal states of Germany.

During the recruitment of the study population, only 28% of all invited schools reported if they want to join the study or not. A three-fold rate did not give a feedback at all. The most likely explanation for this low feedback rate is that schools are busy with class organization prior to the beginning of the school year. Beyond that, structural changes imposed by the Ministries of Education at time of recruitment come to the fore in terms of combining schools and restructuring school types which complicated the situations for schools. Nevertheless, the calculated sample size was accomplished.

After randomisation three classes from control group and 16 classes from intervention group withdrew the consent to participate. Since all of these classes did so after the randomization, it is assumed that schools and teachers probably underestimated the effort and commitment for participating in the study. Unfortunately, two schools of intervention condition that dropped out were *Gymnasiums*. Therefore, a difficulty that might bias outcome effects is the higher proportion of students who attend schools with higher academic requirements in control condition. But distribution represents conservative bias due to assumptions that socioeconomic status as well as a higher education level mediates substance use. Initial conditions seem therefore to be favourable since no baseline difference between conditions were reported, except school type and marginal difference between self-efficacy, empathy and class climate.

The use of self-completed questionnaires could be a limitation to this study. Indeed, the risk of over or under reporting from students or the tendency to project favourable images of oneself (social desirability) are major problems in studies using self-reports. Due to randomization, these potential limiting factors should be evenly distributed over both conditions. Nonetheless, use of self-report is an inevitable procedure when including a large number of participants. Furthermore, general set-ups in this study like anonymisation of information [50], non-involvement of teachers and parents while data assessment might reduce limitation factors.

It is hypothesised that the intervention will lead to an increase of general life skills, refusal skills, and knowledge about substance use. These enhancements should be accompanied

by a lower likelihood of smoking onset and alcohol consumption. By evaluating process, aspects of acceptance, feasibility, and practicability of the programme as well as of fidelity of the implementation will be considered. Teachers' feedbacks can be used for improving materials if necessary. Should we be able to confirm the hypotheses, an effective programme can be implemented in several schools in order to prevent adolescent substance use.

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List of abbreviations

ICC: Intra-class coefficient, WHO: World Health Organization, Cl: Classes, Sch: School

Authors' contributions

JH drafted the manuscript, participated in acquisition of data, and performed statistical analysis and interpretation of data.

RH contributed to study concept and design, study supervision and critical revision of the manuscript for important intellectual content.

KM participated in acquisition of data, and statistical analysis.

BI contributed to study concept and design, study supervision and critical revision of the manuscript for important intellectual content, participated in drafting the manuscript, acquisition of data and its analysis and interpretation.

All authors read and approved the final manuscript.

Funding statement

The „Eigenständig werden" prevention trial is funded by German Cancer Aid as one of five projects in the Priority Program Primary Prevention of Cancer (Substance use) (No 108374). After a positive decision on applying for study support, the German Cancer Aid did not influence the collection, analysis or interpretation of data or the writing of the article and decision to submit it.

Competing interests

IFT-Nord is responsible both for development and evaluation of the programme "Eigenständig werden".

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Acknowledgements

We would like to thank our partners: Institut für Qualitätsentwicklung an Schulen Schleswig-Holstein, Landesinstitut für Schule Bremen, Krisenhilfe Bochum, Fachstelle für Suchtprävention im Wetteraukreis, Fachstelle für Suchtprävention des Zweckverbandes der Diakonie Bad Hersfeld, Diakonie Herford, Koordinationsstelle Schulische Suchtvorbeugung, Fachstelle für Suchtvorbeugung Dortmund, Hessische Landesstelle für Suchtfragen, Ginko Stiftung für Prävention, and all schools that participate in the study.

Figure legends

Figure 1. Flowchart.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n.a.
Participants	4a	Eligibility criteria for participants	9
	4b	Settings and locations where the data were collected	14-15
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11-14
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n.a.
Sample size	7a	How sample size was determined	8
	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	10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10
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	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	n.a.

		assessing outcomes) and how	
	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	16
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	18
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	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	n.a.
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	n.a.
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)	16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n.a.
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n.a.
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n.a.
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18-20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	n.a.
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	n.a.
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	n.a.
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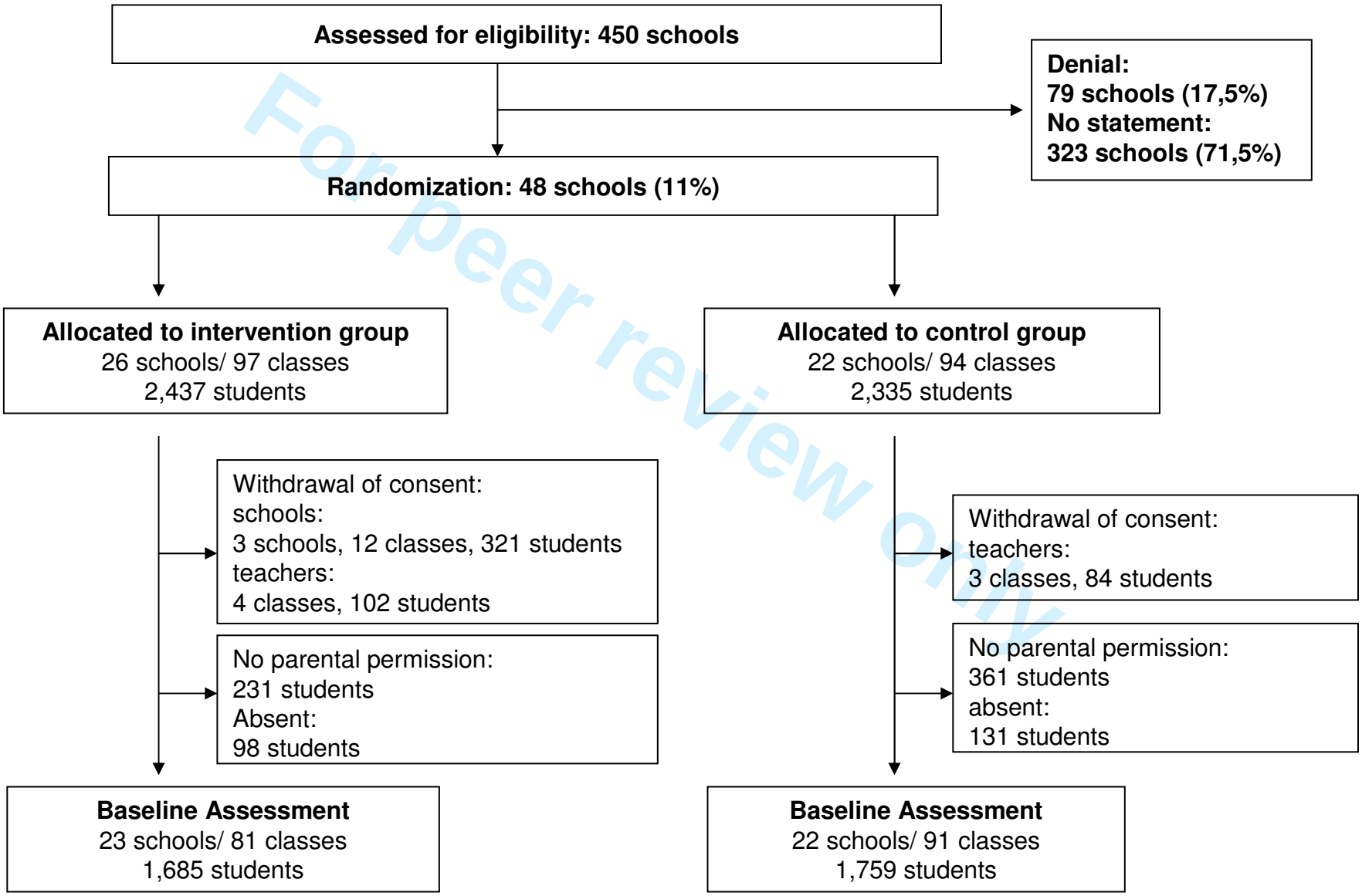
*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.



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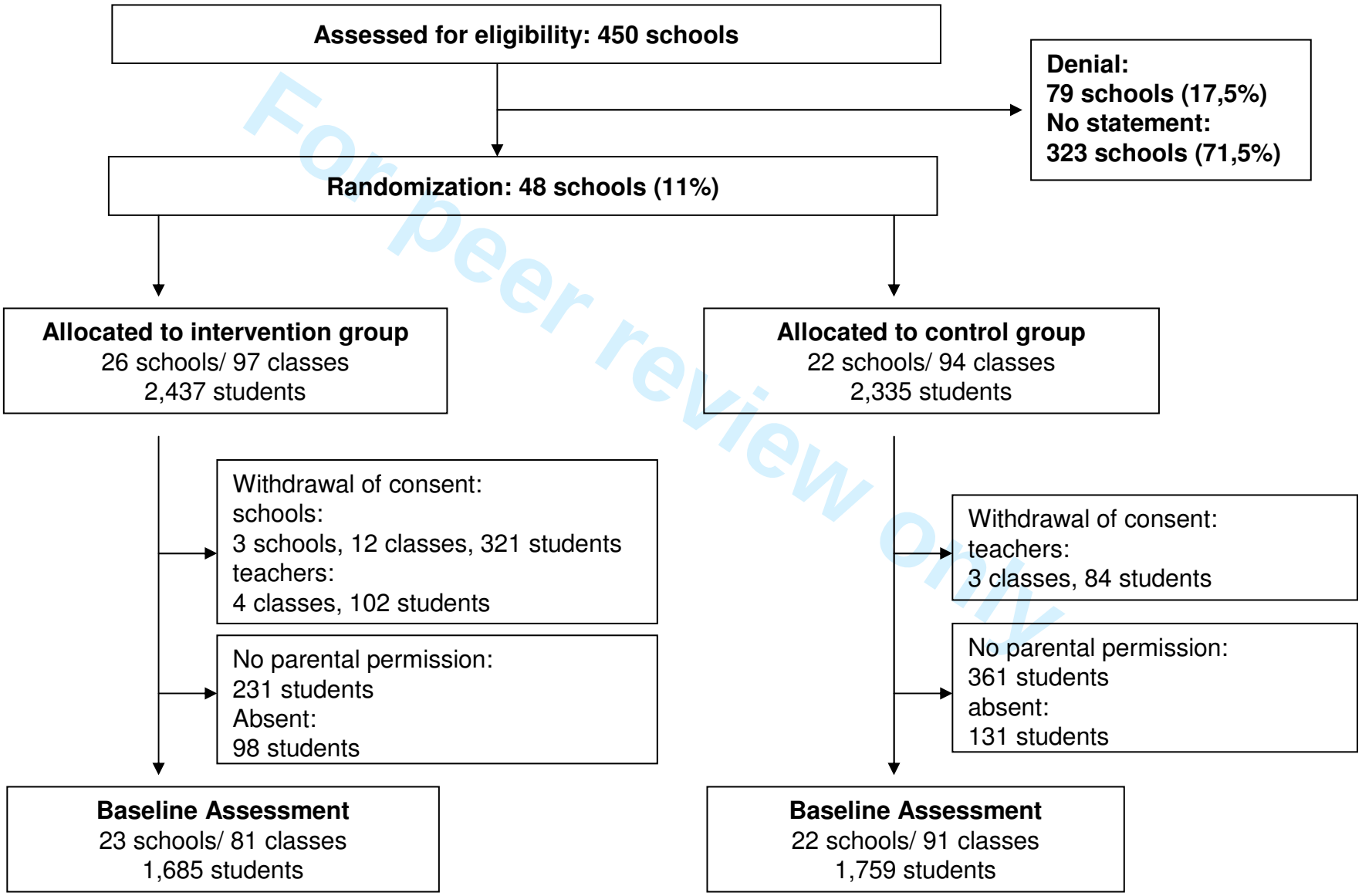
The „Eigenständig werden" prevention trial: a cluster randomised controlled study on a school-based life skills programme to prevent substance use onset.

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2011-000352.R1
Article Type:	Research
Date Submitted by the Author:	21-Sep-2011
Complete List of Authors:	Hansen, Julia; Institute for Therapy and Health Research, IFT-Nord Hanewinkel, Reiner; Institute for Therapy and Health Research, IFT-Nord Maruska, Karin; Institute for Therapy and Health Research, IFT-Nord Isensee, Barbara; Institute for Therapy and Health Research, IFT-Nord
Primary Subject Heading:	Public health
Keywords:	school-based prevention programme, general life skills, substance use



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The „Eigenständig werden“ prevention trial: a cluster randomised controlled study on a school-based life skills programme to prevent substance use onset

Study protocol and baseline characteristics

Abstract

Background

The aim of this study is the implementation and evaluation of “Eigenständig werden 5+6” (“Becoming Independent 5+6”), a school-based curriculum for grade 5 and 6 developed upon evidence-based criteria for effective drug prevention curricula in schools. Evaluation of the programme includes efficacy, feasibility, and practicability in daily school routine.

Methods and analysis

The intervention “Eigenständig werden 5+6” consists of 14 teaching units evenly distributed over grades five and six which are interactively delivered, and a parent component. Programme effects are studied in a four wave cluster randomised controlled trial with two arms, an intervention and a control condition. Self-completed questionnaires from students and teachers are collected by trained research staff.

45 schools, 172 classes and 3,444 students with a mean age of 10.37 years (SD=.59) and 47.9% girls from four federal states in Germany were assessed at baseline. 1,685 students in 81 classes were assigned to intervention classes, 1,759 students in 91 classes to control arm.

No differences between conditions were either found for age, gender, immigration background, socio-economic status, substance use, or life skills at baseline. Exceptions are higher self-efficacy (t(3438)=2.34, p=.02, d=.08) and empathy (t(3302)=2.4, p=.02, d=.09) reported for control group whereas class climate seems better in intervention condition (t(3037)=2.01, p=.05, d=.07), but effect sizes state marginal differences.

Ethics and dissemination

Ethical approval was granted by the Ethics Committee of the Medical Faculty of the University of Kiel. The study was approved by respective Ministries of Education.

Conclusion

Baseline data suggest that the initial conditions are favourable for testing programme efficacy since distribution of baseline levels of the outcomes does not differ in intervention and control condition, except negligible differences between self-efficacy and empathy higher in the

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control group and class climate higher in the intervention group.

Trial registration: Current Controlled Trials ISRCTN99442407

Article Summary

Article focus

- The focus of this study is to implement and evaluate a school-based curriculum for students in grade five and six, developed upon evidence-based criteria for effective drug prevention curricula in schools.
- It is hypothesised that the intervention will lead to an increase of general life skills, refusal skills, and knowledge about substance use. These enhancements should be accompanied by a lower likelihood of smoking onset and alcohol consumption.

Key messages

- Due to inconsistent results concerning long-term effects and effective programme components of school-based prevention programmes, there is a need for further research in this field. This trial addresses this need.

Strengths and limitations

- Strengths:

o This cluster randomised controlled trial includes a large sample of adolescents.

o A wide spectrum of outcomes and confounders will be assessed in four waves including not only post-test but also follow-up

Limitations:

o Self-reports of students may be a limiting factor to this study.

BACKGROUND

Introduction

Albeit lifetime smoking prevalence at the age between 12 and 17 years has declined in Germany over the last decade [1], substance abuse is still one of the major threats to adolescent's health in Germany and Western cultures in general [2,3]. In particular, tobacco smoking and alcohol consumption are serious problems not only for adolescent but also for adulthood health considering that juvenile behavioural pattern such as smoking will presumably establish itself in adulthood, since the majority of adult smokers report having started at an early age [4-6]. Especially adolescents aged between 12 and 14 years represent the high risk group for an onset of alcohol consumption and smoking initiation. Preventing juvenile substance use is therefore an important aim to avoid premature mortality and morbidity and to pave the way for a healthy lifestyle.

School-based prevention programs are considered to be one of the most appropriate and suitable strategies to tackle substance use [7-9]. Informational programs seem not as effective as those that focus on psychosocial strategies and educate adolescents about social norms and influences [10]. Another promising approach to promote a healthy lifestyle is the development and improvement of general life skills [11], skills for resisting social influence and substance-specific skills in adolescence [12]. General life skills empower adolescents in challenging situations, help to master life as competent as possible as well as to deal effectively with the realities of life, and help to prevent substance use and addiction. Enabling children to acquire knowledge and developing attitudes and life skills which support the adoption of healthy behaviours is an approach strongly recommended by the World Health Organization (WHO) [13]. For this reason, some primary prevention programs are based on the life skills approach even though the empirical evidence of the efficacy of these programs is rather weak [14]. Research on effective program components as well as on long-term effects have shown inconsistent results [7,15,16] and further research is needed.

Aims and hypotheses

The focus of this study is to implement and evaluate a school-based curriculum for students in grade five and six, developed upon evidence-based criteria for effective drug prevention curricula in schools. The overall aim of this school-based curriculum is the prevention of substance use and addiction by increasing substance specific skills and general life skills of students in grade five and six. To evaluate effects as well as feasibility and practicability of the program, a four-wave controlled study is conducted in daily school routine.

“Eigenständig werden 5+6” (“Becoming independent 5+6”) is a universal school-based prevention program for grade five and six based on the social influence model and on the life skills approach. It contains substance-specific as well as substance-unspecific elements and takes quality criteria of effective prevention programs into account [8,17-19]. It is expected that participation in the prevention program will lead to lower rates of adolescent’s smoking initiation and to abstinence from alcohol or at least to a more responsible consumption. The program is designed to address both the social and psychological factors promoting the onset of tobacco smoking and drinking alcohol by attempting to increase the students' ability to cope with pressures to smoke and to drink and to decrease student’s susceptibility to pro-smoking and pro-alcohol social influences. It targets at the improvement of students’ refusal skills and their ability to cope with emotions, stress and problems. Overall, dependent variables to be influenced by the prevention program are use of tobacco and alcohol, smoking-related and alcohol-related knowledge, intentions and attitudes towards substance use, susceptibility to smoking cigarettes and alcohol and general life skills, social skills as well as substance-specific refusal skills.

METHODS AND ANALYSIS

Intervention

”Eigenständig werden 5+6” was designed by an interdisciplinary team of psychologists, sports scientists and pedagogues. The prevention program consists of twelve 45- to 90-

minute units. The units are evenly distributed over grades five and six and include the following components: life skills (i.e. problem solving, critical thinking, effective communication skills, decision-making, interpersonal relationship skills, self-awareness building skills, empathy, coping with stress, and emotions), student's ability to work in a group and substance specific skills. To facilitate the accomplishment of the prevention program, an order of units was predetermined.

In addition, alcohol and smoking are addressed in two workshops lasting four till six hours. The workshops include several activities about substance use such as smoking cigarettes and alcohol abuse, and will be carried out at the end of grade five and six. Profound knowledge and skills will be conveyed in these workshops by providing different learning stations for students. Students can choose in what order they do the stations but are required to complete all of them. At the end of grade five, tobacco smoking is the general topic whereas alcohol consumption will be addressed at the end of grade six. Table 1 displays an overview of the interventions' contents.

Table 1. Overview of interventions' contents.

Parent evening 1: Overall introduction to the programme		
Unit	Length/ Contents	Parent leaflet (contents)
5.1 Klasse sein - Gemeinschaft werden (Class community)	45 min: introduction, familiarisation, relationships	Introduction to the programme and overview
5.2 Klassenregeln (Class rules)	90 min: development of class rules, incentives and sanctions	Explanation for the need of rules
5.3 Miteinander sprechen (Communication)	90 min: communication skills and self-assertion	--
5.4 Feedback (Feedback)	90 min: how to provide and get feedback	--
5.5 Klassenrat (Class board)	45 min: introduction of a class board, social learning	Introduction of a family board
5.6 Und was jetzt? (How to solve problems)	90 min: learning of a useful strategy of solving problems (five-finger-strategy)	Introduction of the five-finger-strategy
5.7 Weniger ist mehr/Liebe Gewohnheiten (Less is more-beloved habits)	135 min: developing awareness of addiction, habits, rituals	Explanation for the need of learning about habits, rituals, and addiction
Aktionsparcours Nikotin (Workshop: Smoking cigarettes)	4-6 hours: nine different tasks with topics concerning smoking (e.g. risks, components, consequences of addiction, self-resistance, peer pressure)	Information of rules that help to prevent smoking onset
Parent evening 2: Topic Smoking: Leading Questions: why does the child learn about smoking and how can it be supported?		
6.1 Gemeinsam lernen (Learning together)	90 min: learning to cooperate, working in a team	--
6.2 Mit Gefühl (Sentimentally)	90 min: cognition and expression of comfortable and unpleasant emotions like fear, anger, sadness, happiness	Explanation for the need of expressing emotions
6.3 Stärken stärken (Strengthening my strengths)	90 min: empathy and self-awareness, strengths and weaknesses	How to support the child in recognising its strengths and weaknesses
6.4 Anders sein (Being different)	45 min: learning to accept of being different	--
6.5 Konflikte lösen (Dealing with conflicts)	90 min: learning of a strategy to deal with conflicts in an adequate and peaceful manner	How to support the child in dealing with conflicts
6.6. Stress und Entspannung (Stress and relaxation)	90 min: realising the importance of relaxation, methods to handle stressful situations	How to support the child in handling stressful situations
6.7 Mobbing (Bullying)	90 min: learning of recognising and realising bullying, strategies to prevent it and to help if it occurs	Realising bullying, support the child if it is bullied
Aktionsparcours Alkohol (Workshop: Alcohol)	4-6 hours: nine different tasks with topics concerning alcohol consumption (e.g. risks, consequences of addiction, self-resistance, peer pressure)	Information about rules and support
Parent evening 3: Topic Alcohol: Leading Questions: why does the child learn about alcohol consumption and how can it be supported?		

The entire prevention program is conducted by the teachers in classroom during usual school lessons. Teachers receive a manual which provides specific instructions and background information that is needed to conduct the units and they took part in a two day training course that was carried out by especially qualified prevention experts. To develop life skills, miscellaneous teaching methods, such as interactive didactics, working in small groups, relaxation exercises, pantomime, identification figures, and active games are used. Units as well as workshops include working sheets and several background information and instructions.

Additionally, the program involves parents by providing three parent-teacher conferences and different informational material to keep them informed on their children's subjects. The informational materials include suggestions and rules on how to support their children. To take families with an immigration background into consideration, all parental information are also available in Turkish and Russian.

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Study Design

To evaluate effects of "Eigenständig werden 5+6", a four-wave cluster randomised controlled trial with two arms, an intervention and a control condition, is conducted. The intervention group takes part in the prevention programme and will be compared with the non-treated, "usual curriculum" control group. The actual intervention duration is from the beginning in grade five (October/November 2010) till the end of grade six, spanning a period of two school years. The randomisation occurred at school level to avoid information exchange between the conditions in the schools. Data are collected prior to the start of the intervention (September/October 2010), at the end of grade five (June/July 2011), at the end of grade six (June/July 2012) and in the middle of grade seven (December 2012).

Calculated sample size

The cluster randomised trial involves randomising social units or clusters of individuals rather than individuals themselves. Specific constraints must be considered during planning and analysis [20]. Indeed, the responses of individuals within a cluster tend to be more similar

than those of individuals of different clusters. The clustering effect is defined as $1 + (m - 1)p$, where m is the average number of subjects per cluster and p the intraclass correlation coefficient (ICC) [21]. Values of ICC for smoking and drinking behaviour were taken from the EU Drug Addiction Prevention Trial [22], and were estimated with approximately 0.02, which is in line with other estimations [23].

Power calculations were run with a sample size calculator for cluster randomized trials [24]. Based on earlier experiences, a drop-out rate of 25% was hypothesized. Taking as current estimates, the lifetime smoking prevalence at the age between 12 and 17 years (at the time of the follow-up tests the age of most students will be approximately 13 till 14 years) was valued with 43% [25], whereas the lifetime prevalence of alcohol consumption at the age between 11 and 17 years was estimated with 64% [26].

Applying a significance level of alpha=0.05, power=0.80, a 15% prevention effect, and an average number of 20 students per class (m), the power calculations resulted in a recommended sample size of 158 classes and 3,160 students.

Sample recruitment

Sample recruitment took place in four German federal states: Schleswig-Holstein, North-Rhine-Westphalia, Hesse and Bremen. In order to achieve a balanced representation of social strata, complete lists of all secondary schools (except schools with students for special needs) of selected regions in Schleswig-Holstein, North-Rhine-Westphalia, and Hesse were obtained from the Ministries of Education of each federal state. In Bremen, all secondary schools were included. Invited school types range from *Gymnasium* which is defined as a school for students who have high academic skills and aim for university-entrance diploma after accomplishment, to *Realschule*, *Hauptschule* and *Regionalschule* that focus on students with lower academic skills compared to *Gymnasium*. After attending elementary school, *Gymnasium* requires 8 till 9 years of school whereas students of *Realschule*, *Hauptschule* or *Regionalschule* need to attend school for 5 till 6 years. Other school types

included are *Gemeinschaftsschule* as well as *Gesamtschule* which offer all kind of degrees and in which students with varying academic skills are taught together.

Invitation letters and information sheets explaining the aims of the study were sent to the head teachers of 450 secondary schools in the study regions. Schools were invited to participate in the trial with all classes in grade five and were sent a detailed memorandum of understanding to sign and to obtain head teachers' written commitment to the trial. The importance of the randomized design was emphasized and it was made clear to schools that it would be preferable for them to decline participation rather than to join the study and withdraw commitment at a later point. Schools agreeing to participate registered for the study by indicating general interest and the number of fifth grade classes interested in the study, the names of the class teachers and the number of students per class. In addition, schools could ask for visits of the project staff to receive first hand information on the requirements of the trial.

323 out of 450 schools invited did neither express approval nor disapproval, whereas 79 schools with approximately 180 fifth grade classes denied their participation mostly due to shortage of time because of structural changes imposed by Ministries of Education. 48 schools (11%) with 191 classes and 4,772 students out of 450 schools invited decided to take part in the study. The highest rate of participation was found for Hesse as 28% of all schools invited decided to join the study. A lower rate can be stated for North-Rhine-Westphalia (15%) and Bremen (14%) as well as for Schleswig-Holstein (8%) where only 18 out of 228 schools agreed to participate.

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. Of these 48 schools agreeing to participate, 26 schools with 97 classes and 2,437 students were allocated to intervention group whereas 22 schools with 94 classes and 2,335 students were assigned to control condition. After randomisation, three schools of intervention group withdrew their consent as well as four

teachers of intervention classes refused to take part. Taking absent students and those with no parental permission into account, baseline data of 23 intervention schools with 81 classes and 1,685 students were available.

In control condition, teachers of three classes withdrew consent, 361 students had no parental permission and 131 were absent at day of data collection. Therefore, baseline data of 22 schools with 91 classes and 1,759 students were collected (see Figure 1).

Thus, 45 schools and 172 classes take part in the study and data of 3,444 students were assessed at baseline altogether. An overall of 592 students were not eligible because of missing parental consent. Considering the recommended sample size, the sample of 172 classes with 3,444 students at baseline fits the results of the power analysis (158 classes with 3,160 students needed).

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Questionnaire

Data was collected through self-completed anonymous questionnaires by teachers and students at baseline, prior to the beginning of the intervention and will be assessed by the same method in further waves.

Questionnaire (students)

The students' questionnaire was developed and designed, pretested and modified prior to the baseline assessment.

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Before starting to develop the questionnaire, a focus group of students (N=7) was interviewed to gain insight into student's environment to detect, for example, typical situations that might be stressful or that cause problems for this age group. This information helped to develop a questionnaire that is appropriate for students in grades five and six. Afterwards, a first version of the questionnaire was pretested in four fifth grade classes (N=95) and additionally in two classes (N=14) in schools for children with special needs to eliminate items hard to understand as well as items with poor psychometric quality.

The final questionnaire assesses outcomes such as use of tobacco and alcohol consumption in forms of current behaviour and lifetime prevalence, smoking-related and alcohol-related knowledge, intentions and attitudes towards substance use, susceptibility to smoking cigarettes and alcohol and general life skills, social skills and substance-specific refusal skills. Questions concerning substance use covered own lifetime smoking prevalence likewise alcohol consumption. Furthermore, frequency of current consumption, episodes of drunkenness and binge drinking were investigated. Knowledge, intentions and attitudes about smoking cigarettes and drinking alcohol, susceptibility along with smoking and alcohol related behaviour of peers and family were included. Confounders like socio-demographic characteristics, bullying, class climate and leisure time behaviour were also assessed at baseline, stable traits like characteristics of personality and general parenting style will be assessed at post-test, due to aspects of feasibility (especially length of questionnaire and time needed for completion).

In general, items included in the questionnaire are based on “standard” questions used in the international literature, in published questionnaires or in own previous research. Table 2 summarizes all variables including references.

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Table 2. Overview of variable constructs.

General life skills	Substance use (Smoking and alcohol)	Additional/Confounders
Communication [27,28]	Smoking-related and alcohol-related knowledge	Socio demographic characteristics [29]
Self esteem [30]	Use of tobacco [31,32]	General parenting style* [33]
Self-efficacy [28]	Use of alcohol [35]	Personality characteristics* [36,37]
Self concept [27]	Intentions and attitudes and normative expectations [38]	Leisure time behaviour [34]
Empathy [39]	Susceptibility [40]	Class climate**
Emotions [41]	Resistance skills [42]	Bullying [43,44]
Stress [45]	Social influence [32,46]	
Problem solving [27]	Perceived parental rules and attitudes [47,48]	

* Assessed at first post-test. ** On the basis of own previous research.

Specific values for the life skills-scales, for intentions, attitudes and perceived risks at baseline along with representative items and used response scales are displayed in table 2. If item-total correlation, difficulty or Cronbach's Alpha exceed limiting values, scales were modified for data analysis by excluding items in order to increase psychometric quality. All values shown in table 3 represent final scales. Stress, problem-solving, and handling emotions will be interpreted on single item level in order to ascertain student's strategies to handle situations and to cluster specific types.

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Table 3. Internal consistency at baseline.

Scales (Item exemplification)	Cronbach's α	Number of Items	Item-total Correlation r_{it}	Item Difficulty P_i in %
Communication *("If I talk to somebody, I will not interrupt him/her")* *Response category: 4 point scale (I do not agree – I agree)*	α =.73	9	.35 - .48	57 - 86
Self esteem *("I sometimes think that I'm no good")* *Response category: 4 point scale (I do not agree – I agree)*	α =.70	5	.25 - .60	60 - 85
Self-efficacy *("Whatever happens, I will handle it")* *Response category: 4 point scale (I do not agree – I agree)*	α =.61	5	.26 - .41	58 - 70
Self concept *("I"m aware of my strengths")* *Response category: 4 point scale (I do not agree – I agree)*	α =.67	8	.27 - .42	55 - 82
Class climate *("We help each other")* *Response category: 4 point scale (I do not agree – I agree)*	α =.73	9	.35 - .48	57 - 86
Bullying *("How often have you taken part in bullying (kicking, beating) another student?")* *Response category: 5 point scale (Never - Few times a week)*	α =.71	3	.51 - .57	5 - 13
Victimization *("How often have you been bullied (kicking, beating) by another student?")* *Response category: 5 point scale (Never - Few times a week)*	α =.78	3	.57 - .67	14 - 22
Smoking-related perceived risks *("I will be sick")* *Response category: 4 point scale (Surely not - Surely yes)*	α =.76	6	.43 - .58	60 - 78
Alcohol-related perceived risks *("I will be sick")* *Response category: 4 point scale (Surely not - Surely yes)*	α =.79	5	.53 - .61	63 - 80

Questionnaire (teachers)

Teachers were asked to complete a questionnaire to assess class climate. They should evaluate working atmosphere including student's ability to work together, concentration, motivation, and pace of work, student's ability to solve problems, the corporate feeling of the class as well as the relationship between students and teachers by assigning marks from 1 (very good) up to 6 (very poor). Cronbach's Alpha of class climate scale is acceptable (α=.86, r_{it}≥.41).

Process evaluation

Teachers of the intervention group will additionally evaluate the implementation of the intervention programme and feasibility of every unit they will conduct. They were instructed while attending the teacher training and received questionnaires to document the process of implementation of "Eigenständig werden 5+6". These questionnaires cover the following information: date and duration of implementation, number of students attending the class, whether each of the core activities was or was not implemented, and a final judgment of the unit. By leaving space for open commentaries, teachers were encouraged to report their opinion on the units and activities as well as for anything else they want to comment. Furthermore, they should appraise the units' age-appropriateness and contents, and students' participation in the units.

Assessment procedure

The assessment was planned by asking schools about their preferred date and time for data collection at the beginning of grade five. Contemporaneously, teachers collected the parental permission of all students in class. In three regions, passive parental permission was used, i.e. parents had to refuse to take part in the study rather than to agree. In one region, an active permission was requested by the respective Ministry, i.e. parents had to agree in case they complied with participation. Teachers registered all names of students with no permission in a list which should be saved in the schools throughout the entire trial. All students with refusal are excluded from all assessments. To permit a linking of individual

information on subsequent surveys while assuring anonymity, each questionnaire is labelled with a seven-digit individual code generated by the student. 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 [49].

Data assessment was conducted in the class room and lasted 45 minutes. Project staff was responsible for the distribution, help in completion and collection of the questionnaire. Teachers were not involved. At the end of the assessment, all questionnaires which were completely filled out were placed in an envelope and sealed in front of the class. Every student was therefore assured that neither teachers nor parents were able to see the completed questionnaire.

79% (2,719) of all students were able to complete the questionnaire in 45 minutes. Students, who were not able to complete the entire questionnaire in 45 minutes, received a prepaid envelope. While the completed pages were collected by the staff, the students marked their own individual code on the last page, completed the unfilled pages of the questionnaire and anonymously sent it back to the project team. 46 % (331) of the students sent the pages back. Taking the questionnaires of absent students as well as afterwards sent pages into account, an overall of 2,922 data sets is complete at baseline. 522 data sets contain missing values on at least one page. Absent students were given a questionnaire and instructions in a prepaid envelope. After completion, they sent it back to the project team. An overall of 180 questionnaires were left in schools for absent students. 95 of these questionnaires (53%) were sent back completely filled out.

Baseline characteristics

A total number of 45 schools, 172 classes and 3,444 students with a mean age of 10.37 years (SD=.59) and 47.9% girls from four federal states in Germany were assessed at baseline. Baseline data suggest that the initial conditions are favourable for testing programme efficacy, since distribution of baseline levels of the outcomes does not differ in intervention and control condition. Exceptions are higher self-efficacy ($t_{(3438)}$=2.34, p=.02,

d=.08) and empathy ($t_{(3302)}$=2.4, p=.01, d=.09) reported for control students, whereas class climate, rated by students, seems better in intervention condition ($t_{(3037)=}$2.01, p=.05, d=.07), but effect sizes state marginal differences. Different distribution between the intervention and the control arm at baseline assessment was also found for school type with a higher proportion of students of *Gymnasiums* in control condition ($X^2_{(1)}$=17.7, p=.001). Differences between the intervention and control condition were neither found for age, gender, immigration background nor socio-economic status. Likewise, no significant differences between intervention and control condition were found for teacher's evaluation of class climate.

Table 4 shows the characteristics of the baseline survey for intervention and control condition and displays test statistics of differences between the conditions. Since responses of students within their classes tend to be more similar than those of students of other classes, the intra-class correlation coefficients for substance use are displayed as well.

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Table 4. Characteristics at the baseline survey.

Baseline characteristics		Group				Difference
		Intervention (n=1,685)		Control (n=1,759)		
		N/ M (SD)	%	N/ M (SD)	%	
Gender	Boys	866	51.5	926	52.8	$X^2_{(1)}$=0.51, p=.48
	Girls	816	48.5	831	47.3	
Age		10.38 (.60)		10.35 (.58)		$t_{(3433)}$=1.27, p=.21
School type	Gymnasium	620	36.8	771	43.7	$X^2_{(1)}$=17.7, p=.001
	Others	1,065	63.2	988	56.3	
	Yes	372	22.3	409	23.3	
Socio-economic status*		4.44 (1.10)		4.44 (1.08)		$t_{(3439)}$=0.01, p=.99
Lifetime smoking	None	1,575	94.4	1,629	93.6	$X^2_{(4)}$=2.6, p=.63 ICC_{Cl}=.02 ICC_{Sch}=.03
	Only a few puffs	51	3.1	63	3.6	
	1 -19 cigarettes	37	2.2	40	2.3	
	20-100 cigarettes	5	.30	5	.29	
	> 100 cigarettes	1	.06	4	.23	
Current smoking	No	1,657	98.8	1,724	98.6	$X^2_{(4)}$=1.5, p=.83 ICC_{Cl}=.01 ICC_{Sch}=.01
	Yes	21	1.2	25	1.4	
Lifetime alcohol consumption	No	1,089	65.3	1,107	63.6	$X^2_{(2)}$=1.8, p=.40 ICC_{Cl}=.05 ICC_{Sch}=.02
	Yes	576	34.5	631	36.3	
Lifetime alcohol consumption without parent's knowledge	No	1,603	96.0	1,673	96.1	$X^2_{(1)}$=1.02, p=.60 ICC_{Cl}=.09 ICC_{Sch}=.02
	Yes	64	4.0	67	3.9	
Current alcohol consumption ("in the last 30 days")	Never	1,572	94.1	1,642	94.4	$X^2_{(2)}$=1.6, p=.44 ICC_{Cl}=.01 ICC_{Sch}=.004
	On 1-2 days a month	85	5.1	77	4.4	
	≥3 days a month	14	0.8	20	1.2	

*Socio-economic status was measured by Family Affluence Scale [29]; sum of two items: (range from 0 up to 3, a higher mean represents a higher socio-economic status). Abbreviation: Cl=classes, Sch=scho

Statistical analysis

To test efficacy of the programme and to give consideration to cluster effects, i. e. higher similarity of responses within a cluster than between different clusters, multilevel modelling will be carried out. Therefore, 4-level models including levels of school, classes, individuals, and waves with random intercepts for school, classes and individuals will be conducted. Condition and covariates will be considered as fixed effects.

In order to test effective programme components mediation analysis will be performed. In a first step, it can be analysed if the lessons of prevention programme have affected what they ought to affect: Students of the intervention group should have higher substance-specific competencies and also higher substance-unspecific skills. In a second step, it can be analysed if a given change in substance use (=dependent variable) in the intervention group is mediated by (1) the substance-specific skills, (2) the substance-unspecific skills, (3) by both, or (4) by neither nor.

Attrition analyses will be conducted to compare students who retain in intervention with the students lost to follow up and test for differences between conditions.

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ETHICS AND DISSEMINATION

Prior to the evaluation, the trial was approved and registered by the ethics committee of the Medical Faculty of the University of Kiel (AZ D 419/10) and approved by Ministries of Education. Parents were fully informed about the trial and its aim. Depending on the federal state, parental consent had to be given either in form of an active agreement or in form of a passive agreement. Students with no parental consent are excluded from all assessments. Anonymity is assured by using a seven-digit individual code that is generated by each student. The assessments are optional and each student can deny completing the questionnaire without any explanation.

CONCLUSION

The aim of the “Eigenständig werden 5+6” trial is to evaluate the efficacy of a school-based prevention program for substance use. It involves more than 3,000 students from four federal states of Germany.

During the recruitment of the study population, only 28% of all invited schools reported if they want to join the study or not. A three-fold rate did not give a feedback at all. The most likely explanation for this low feedback rate is that schools are busy with class organization prior to the beginning of the school year. Beyond that, structural changes imposed by the Ministries of Education at time of recruitment come to the fore in terms of combining schools and restructuring school types which complicated the situations for schools. Nevertheless, the calculated sample size was accomplished.

After randomisation three classes from control group and 16 classes from intervention group withdrew the consent to participate. Since all of these classes did so after the randomization, it is assumed that schools and teachers probably underestimated the effort and commitment for participating in the study. Unfortunately, two schools of intervention condition that dropped out were *Gymnasiums*. Therefore, a difficulty that might bias outcome effects is the higher proportion of students who attend schools with higher academic requirements in control condition. But distribution represents conservative bias due to assumptions that socioeconomic status as well as a higher education level mediates substance use. Initial conditions seem therefore to be favourable since no baseline difference between conditions were reported, except school type and marginal difference between self-efficacy, empathy and class climate.

The use of self-completed questionnaires could be a limitation to this study. Indeed, the risk of over or under reporting from students or the tendency to project favourable images of oneself (social desirability) are major problems in studies using self-reports. Due to randomization, these potential limiting factors should be evenly distributed over both conditions. Nonetheless, use of self-report is an inevitable procedure when including a large

number of participants. Furthermore, general set-ups in this study like anonymisation of information [50], non-involvement of teachers and parents while data assessment might reduce limitation factors.

It is hypothesised that the intervention will lead to an increase of general life skills, refusal skills, and knowledge about substance use. These enhancements should be accompanied by a lower likelihood of smoking onset and alcohol consumption. By evaluating process, aspects of acceptance, feasibility, and practicability of the programme as well as of fidelity of the implementation will be considered. Teachers' feedbacks can be used for improving materials if necessary. Should we be able to confirm the hypotheses, an effective programme can be implemented in several schools in order to prevent adolescent substance use.

This work was supported by German Cancer Aid, grant number No. 108374. The authors have declared no competing interests.

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Contributor Statement

JH drafted the manuscript, participated in acquisition of data, and performed statistical analysis and interpretation of data.
RH contributed to study concept and design, study supervision and critical revision of the manuscript for important intellectual content.
KM developed and pretested the questionnaire, participated in acquisition of data and statistical analysis, and critically revised the manuscript.
BI contributed to study concept and design, study supervision and critical revision of the manuscript for important intellectual content, participated in drafting the manuscript, acquisition of data and its analysis and interpretation.
All authors read and approved the final manuscript.

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List of abbreviations

ICC: Intra-class coefficient, WHO: World Health Organization, Cl: Classes, Sch: School

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Figure legends

Figure 1. Flowchart.

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