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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

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ABSTRACT

Objective: To implement and evaluate 'Eigenständig werden 5+6' ('Becoming Independent 5+6'), a school-based curriculum for grades 5 and 6 developed on the basis of 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 results: The intervention 'Eigenständig werden 5+6' consists of 14 teaching units evenly distributed over grades 5 and 6 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 group. Self-completed questionnaires from students and teachers are collected by trained research staff. 45 schools, 172 classes and 3444 students with a mean age of 10.37 years (SD=0.59) and 47.9% girls from four federal states in Germany were assessed at baseline. 1685 students in 81 classes were assigned to intervention classes, 1759 students in 91 classes to the control arm. No differences between conditions were found for age, gender, immigration background, socioeconomic status, substance use or life skills at baseline. Exceptions were higher self-efficacy ($t(3438)=2.34$, $p=0.02$, $d=0.08$) and empathy ($t(3302)=2.4$, $p=0.02$, $d=0.09$) in the control group, whereas class climate seemed better in the intervention group ($t(3037)=2.01$, $p=0.05$, $d=0.07$), but effect sizes state marginal differences.

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

Trial registration number: Current Controlled Trials ISRCTN99442407.

ARTICLE SUMMARY

Article focus

- The focus of this study was to implement and evaluate a school-based curriculum for students in grades 5 and 6, developed on 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 of this study

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

BACKGROUND

Introduction

Although lifetime smoking prevalence at age 12–17 years has declined in Germany over the last decade,[1] substance abuse is still one of the major threats to adolescent 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, as a 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] Adolescents aged 12–14 years are a high risk group for onset of alcohol consumption and smoking initiation. Preventing juvenile substance use is therefore important in order to avoid premature mortality and morbidity and to pave the way for a healthy lifestyle.

School-based prevention programmes are considered to be one of the most appropriate and suitable strategies to tackle substance use.[7–9] Informational programmes seem not as effective as those that focus on psychosocial strategies and educate adolescents about social norms and influences.[10] Another promising approach to promoting 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, and help them to master life as competently as possible as well as to deal effectively with the realities of life, and also help to prevent substance use and addiction. Enabling children to acquire knowledge and develop 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 programmes are based on the life skills approach, even though the empirical evidence of the efficacy of these programmes is rather weak.[14] Research on effective programme 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 grades 5 and 6, developed on the basis of 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 grades 5 and 6. To evaluate effects as well as feasibility and practicability of the programme, a four-wave controlled study is being conducted in the daily school routine.

'Eigenständig werden 5+6' ('Becoming independent 5+6') is a universal school-based prevention programme for grades 5 and 6 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 programmes into account.[8 17–19] It is expected that participation in the prevention programme will lead to lower rates of initiation into adolescent smoking and to abstinence from alcohol, or at least a more responsible consumption. The programme 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 students' susceptibility to pro-smoking and pro-alcohol social influences. It targets 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 programme 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 and 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 programme consists of twelve 45–90-minute units. The units are evenly distributed over grades 5 and 6 and include the following components: life skills (ie, problem solving, critical thinking, effective communication skills, decision-making, interpersonal relationship skills, self-awareness building skills, empathy, coping with stress, and emotions); the student's ability to work in a group; and substance specific skills. To facilitate the accomplishment of the prevention programme, an order of units was predetermined.

In addition, alcohol and smoking are addressed in two workshops lasting 4–6 hours. The workshops include several activities about substance use (smoking and alcohol), and will be carried out at the end of grades 5 and 6. 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 5, tobacco smoking is the general topic, whereas alcohol consumption will be addressed at the end of grade 6. Table 1 shows an overview of the interventions' contents.

The entire prevention programme 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; 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 background information, instructions and working sheets.

Additionally, the programme involves parents by providing three parent–teacher conferences and informational material to keep them informed on their children's subjects. The informational materials include suggestions and rules on how to support their children. For families with an immigration background, all parental information is 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,

Table 1 Overview of contents of the intervention

Unit	Length/contents	Parent leaflet (contents)
Parent-teacher conference 1: Overall introduction to the programme		
5.1 Class community	45 min: introduction, familiarisation, relationships	Introduction to the programme and overview
5.2 Class rules	90 min: development of class rules, incentives and sanctions	Explanation for the need of rules
5.3 Communication	90 min: communication skills and self-assertion	–
5.4 Feedback	90 min: how to provide and get feedback	–
5.5 Class board	45 min: introduction of a class board, social learning	Introduction of a family board
5.6 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 Less is more/beloved habits	135 min: developing awareness of addiction, habits, rituals	Explanation for the need of learning about habits, rituals, and addiction
Workshop: Smoking cigarettes	4–6 h: nine different tasks with topics concerning smoking (eg, risks, components, consequences of addiction, self-resistance, peer pressure)	Information of rules that help to prevent smoking onset
Parent-teacher conference 2: Topic Smoking: Leading questions: why does the child learn about smoking and how can it be supported?		
6.1 Learning together	90 min: learning to cooperate, working in a team	–
6.2 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 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 Being different	45 min: learning to accept being different	–
6.5 Dealing with conflicts	90 min: learning a strategy to deal with conflicts in an adequate and peaceful manner	How to support the child in dealing with conflicts
6.6. 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 Bullying	90 min: learning to recognise and realise bullying, strategies to prevent it and to help if it occurs	Realising bullying, support the child if it is bullied
Workshop: Alcohol	4–6 h: nine different tasks with topics concerning alcohol consumption (eg, risks, consequences of addiction, self-resistance, peer pressure)	Information about rules and support
Parent-teacher conference 3: Topic Alcohol: Leading questions: why does the child learn about alcohol consumption and how can it be supported?		

an intervention and a control condition, is being conducted. The intervention group taking part in the prevention programme is compared with the non-treated, 'usual curriculum' control group. The actual intervention duration is from the beginning of grade 5 (October/November 2010) until the end of grade 6, spanning a period of two school years. The randomisation occurred at school level to avoid information exchange between the groups in the schools. Data are being collected prior to the start of the intervention (September/October 2010), at the end of grade 5 (June/July 2011), at the end of grade 6 (June/July 2012) and in the middle of grade 7 (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 intra-class 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 0.02, which is in line with other estimations.[23]

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

Applying a significance level of α=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 3160 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 for students with 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 8–9 years of school, whereas students of *Realschule*, *Hauptschule* or *Regionalschule* need to attend school for 5–6 years. Other school types included are *Gemeinschaftsschule* as well as *Gesamtschule*, which offer all kinds 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 5, and were sent a detailed memorandum of understanding to sign and to obtain head teachers' written commitment to the trial. The importance of the randomised design was emphasised 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.

A total of 323 out of 450 schools invited expressed neither approval nor disapproval, whereas 79 schools with approximately 180 fifth grade classes declined to participate, mostly due to shortage of time because of structural changes imposed by Ministries of Education. Forty-eight schools (11%) with 191 classes and 4772 students out of 450 schools invited decided to take part in the study. The highest rate of participation was found for Hesse: 28% of all schools invited decided to join the study. There was a lower rate in North-Rhine-Westphalia (15%) and Bremen (14%), as well as 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% chance of being allocated to either group by using the coin toss method. Of these 48 schools agreeing to participate, 26 schools with 97 classes and 2437 students were allocated to the intervention group, whereas 22 schools with 94 classes and 2335 students were assigned to the control group. After randomisation, three schools in the intervention group withdrew their consent, and 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 1685 students were available.

In the control group, teachers of three classes withdrew consent, 361 students had no parental permission and 131 were absent on the day of data collection. Therefore, baseline data of 22 schools with 91 classes and 1759 students were collected (see figure 1).

Thus, 45 schools and 172 classes took part in the study, and data on a total of 3444 students were assessed at baseline. Overall 592 students were not eligible because of missing parental consent. Considering the recommended sample size, the sample of 172 classes with 3444 students at baseline fits the results of the power analysis (158 classes with 3160 students needed).

Questionnaire

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

Questionnaire (students)

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

Before starting to develop the questionnaire, a focus group of students (N=7) was interviewed to gain insight into the students' 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 5 and 6. 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.

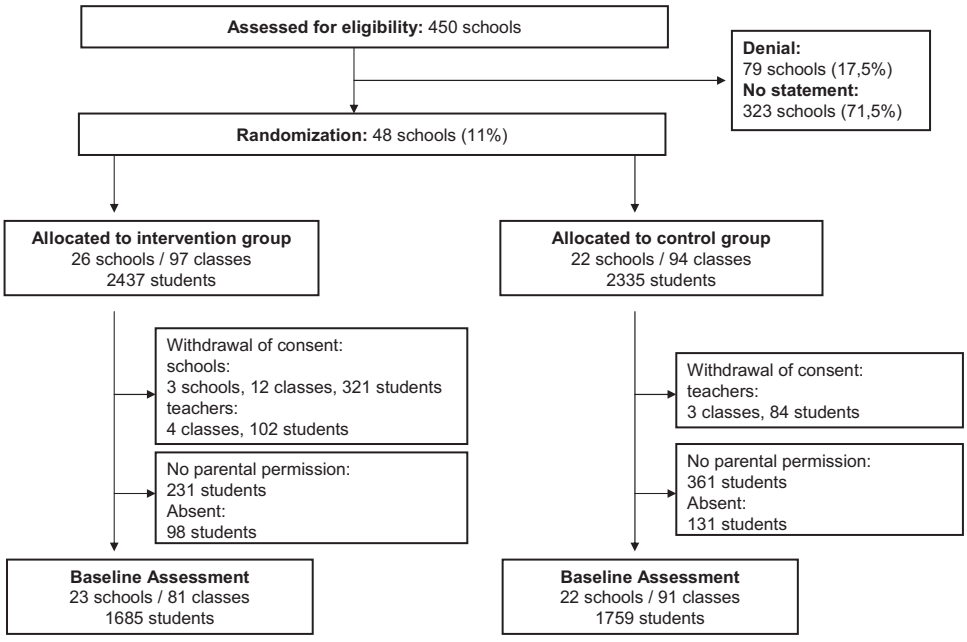

Figure 1 Flowchart of the study design.

The final questionnaire assesses outcomes such as use of tobacco and alcohol consumption in terms 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, and likewise for 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, and susceptibility along with smoking and alcohol related behaviour of peers and family were included. Confounders like sociodemographic 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 post-test, due to 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 our own previous research. Table 2 summarises all variables.

Specific values for the life skills-scales, and for intentions, attitudes and perceived risks at baseline along with representative items and used response scales are shown in table 2. If item-total correlation, difficulty or Cronbach's alpha exceed limiting values, scales are 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 at the single item level in order to ascertain students' strategies to handle situations and to cluster specific types.

Questionnaire (teachers)

Teachers were asked to complete a questionnaire to assess class climate. They were required to evaluate the working atmosphere, including students' ability to work together, concentration, motivation and pace of work;

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	Sociodemographic characteristics[29]
Self-esteem[30]	Use of tobacco[31 32]	General parenting style*[33]
Self-efficacy[28]	Use of alcohol[34]	Personality characteristics*[35 36]
Self-concept[27]	Intentions and attitudes and normative expectations[37]	Leisure time behaviour[38]
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.

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=0.73	9	0.35–0.48	57–86
Self-esteem ("I sometimes think that I'm no good") Response category: 4-point scale (I do not agree–I agree)	α=0.70	5	0.25–0.60	60–85
Self-efficacy ("Whatever happens, I will handle it") Response category: 4-point scale (I do not agree–I agree)	α=0.61	5	0.26–0.41	58–70
Self-concept ("I'm aware of my strengths") Response category: 4-point scale (I do not agree–I agree)	α=0.67	8	0.27–0.42	55–82
Class climate ("We help each other") Response category: 4-point scale (I do not agree–I agree)	α=0.73	9	0.35–0.48	57–86
Bullying ("How often have you taken part in bullying (kicked, beaten) another student?") Response category: 5-point scale (Never–Few times a week)	α=0.71	3	0.51–0.57	5–13
Victimisation ("How often have you been bullied (kicking, beating) by another student?") Response category: 5-point scale (Never–Few times a week)	α=0.78	3	0.57–0.67	14–22
Smoking-related perceived risks ("I will be sick") Response category: 4-point scale (Surely not–Surely yes)	α=0.76	6	0.43–0.58	60–78
Alcohol-related perceived risks ("I will be sick") Response category: 4-point scale (Surely not–Surely yes)	α=0.79	5	0.53–0.61	63–80

students' ability to solve problems, and 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 was acceptable (α=0.86, $r_{it} \geq 0.41$).

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 judgement of the unit. By leaving space for open commentaries, teachers were encouraged to report their opinion on the units and activities as well as anything else on which they want to comment. Furthermore, they were instructed to 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 5. Contemporaneously, teachers collected the parental permission of all students in class. In three regions, passive parental permission was used—that is, 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—that is, parents had to state that they comply 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 has therefore been inspected and approved by ethics committees, data protection and Ministries of Education repeatedly.[49]

Data assessment was conducted in the classroom and lasted 45 min. Project staff were 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.

A total of 79% (2719) of all students were able to complete the questionnaire in 45 min. Students who were not able to complete the entire questionnaire in 45 min, 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 the pages sent later into account, a total of 2922 datasets are complete at baseline. A total of 522 datasets 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. A total of 180 questionnaires were left in schools for absent students. Ninety-five of these questionnaires (53%) were sent back completely filled out.

Baseline characteristics

A total number of 45 schools, 172 classes and 3444 students, with a mean age of 10.37 years (SD=0.59) 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 the intervention and control groups. Exceptions are higher self-efficacy ($t_{(3438)}=2.34$, p=0.02, d=0.08) and empathy ($t_{(3302)}=2.4$, p=0.01, d=0.09) reported for control students, whereas class climate, rated by students, seems better in the intervention group ($t_{(3037)}=2.01$, p=0.05, d=0.07), but effect sizes state marginal differences. A 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 the control group ($\chi^2_{(1)}=17.7$, p=0.001). No differences between the intervention and control group were found for age, gender, immigration background or socioeconomic status. Likewise, no significant differences between the intervention and control group were found for the teacher's evaluation of class climate.

Table 4 shows the characteristics of the baseline survey for the intervention and control group and also test statistics of differences between the groups. Since responses of students within their classes tend to be more similar than those of students of other classes, the ICCs for substance use are shown as well.

Statistical analysis

To test efficacy of the programme and to give consideration to cluster effects—that is, higher similarity of responses within a cluster than between different clusters, multilevel modelling will be carried out. Therefore, four-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 whether the lessons of the prevention programme have affected what they were intended 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 whether 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) both, or (4) neither.

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

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 the Ministries of Education. Parents were fully informed about the trial and its aim. Depending on the federal state, parental consent had to be given in the form of either an active agreement or 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 decline to complete the questionnaire, without explanation.

CONCLUSION

The aim of the 'Eigenständig werden 5+6' trial is to evaluate the efficacy of a school-based prevention programme for substance use. It involves more than 3000 students from four federal states of Germany.

During the recruitment of the study population, only 28% of all invited schools reported whether they wanted to join the study or not. More than 70% of schools gave no 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.

Table 4 Characteristics at the baseline survey

Baseline characteristics	Group: Intervention (n=1685) N/M (SD)	%	Control (n=1759) N/M (SD)	%	Difference
Gender					
Boys	866	51.5	926	52.7	$\chi^2_{(1)}$=0.5, p=0.48
Girls	816	48.5	831	47.3	
Age	10.38 (0.60)		10.35 (0.58)		$t_{(3433)}$=1.27, p=0.21
School type					
Gymnasium	620	36.8	771	43.7	$\chi^2_{(1)}$=17.7, p=0.001
Others	1065	63.2	988	56.3	
Yes	372	22.3	409	23.3	
Immigration background					
No	1291	77.7	1343	76.7	χ^2(1)=0.46, p=0.50
Socioeconomic status*	4.44 (1.10)		4.44 (1.08)		$t_{(3439)}$=0.01, p=0.99
Lifetime smoking					
None	1575	94.4	1629	93.6	
Only a few puffs	51	3.1	63	3.6	$\chi^2_{(4)}$=2.6, p=0.63
1–19 cigarettes	37	2.2	40	2.3	ICC_{Cl}=0.02
20–100 cigarettes	5	0.30	5	0.29	ICC_{Sch}=0.03
>100 cigarettes	1	0.06	4	0.23	
Current smoking					
No	1657	98.8	1724	98.6	$\chi^2_{(1)}$=0.2, p=0.65
Yes	21	1.2	25	1.4	ICC_{Cl}=0.01
Lifetime alcohol consumption					ICC_{Sch}=0.01
No	1089	65.4	1107	63.7	$\chi^2_{(1)}$=1.1, p=0.30
Yes	576	34.6	631	36.3	ICC_{Cl}=0.05
					ICC_{Sch}=0.02
Lifetime alcohol consumption without parents' knowledge					
No	1603	96.0	1673	96.1	$\chi^2_{(1)}$=0.1, p=0.81
Yes	67	4.0	67	3.9	ICC_{Cl}=0.09
					ICC_{Sch}=0.02
Current alcohol consumption ('in the last 30 days')					
Never	1572	94.1	1642	94.4	$\chi^2_{(2)}$=1.6, p=0.44
On 1–2 days a month	85	5.1	77	4.4	ICC_{Cl}=0.01
≥3 days a month	14	0.8	20	1.2	ICC_{Sch}=0.004

*Socioeconomic status was measured by Family Affluence Scale[29]; sum of two items (range 0–3, a higher mean represents a higher socioeconomic status).
Cl, classes; Sch, school.

After randomisation, three classes from the control group and 16 classes from the intervention group withdrew the consent to participate. Since all of these classes did so after the randomisation, it is assumed that schools and teachers probably underestimated the effort and commitment for participating in the study. Unfortunately, two schools in the intervention group that dropped out were *Gymnasiums*. A potential difficulty is that the higher proportion of students who attend schools with higher academic requirements in the control group might bias outcome effects. However, the distribution represents a conservative bias due to assumptions that socioeconomic status as well as a higher education level mediate substance use. Initial conditions seem therefore to be favourable since no baseline differences between conditions were reported, except for school type and a 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 randomisation, 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, such as anonymisation of information,[50] and non-involvement of teachers and parents during 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. During the evaluation process, aspects of acceptance, feasibility and practicability of the programme, as well as 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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Contributors 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, and 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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The 'Eigenständig werden' prevention trial: a cluster randomised controlled study on a school-based life skills programme to prevent substance use onset

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