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Original research

Evaluation of a medical student-delivered smoking prevention program utilizing a face-aging mobile app for secondary schools in Germany: The Education Against Tobacco cluster-randomized controlled trial☆

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ABSTRACT

Background: To reduce smoking uptake in adolescents, the medical students' network Education Against Tobacco (EAT) has developed a school-based intervention involving a face-aging mobile app (Smokerface).
Methods: A two-arm cluster-randomized controlled trial was conducted, evaluating the 2016 EAT intervention, which employed the mobile app Smokerface and which was delivered by medical students. Schools were

☆ Trial Registration: The Education Against Tobacco randomized trial is registered at the US National Institutes of Health (ClinicalTrials.gov) # NCT02697409.

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Prevention
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randomized to intervention or control group. Surveys were conducted at baseline (pre-intervention) and at 9, 16, and 24 months post-intervention via paper & pencil questionnaires. The primary outcome was the difference in within-group changes in smoking prevalence between intervention and control group at 24 months.
Results: Overall, 144 German secondary schools comprising 11,286 pupils participated in the baseline survey, of which 100 schools participated in the baseline and at least one of the follow-up surveys, yielding 7437 pupils in the analysis sample. After 24 months, smoking prevalence was numerically lower in the intervention group compared to control group (12.9 % vs. 14.3 %); however, between-group differences in change in smoking prevalence between baseline and 24-months follow-up (OR=0.83, 95 %-CI: 0.64–1.09) were not statistically significant ($p = 0.176$). Intention to start smoking among baseline non-smokers declined non-significantly in the intervention group ($p = 0.064$), and remained essentially unchanged in the control group, but between-group differences in changes at the 24-months follow-up (OR=0.88, 0.64–1.21) were not statistically significant ($p = 0.417$).
Conclusion: While a trend towards beneficial effects of the intervention regarding smoking prevalence as well as intention to start smoking among baseline non-smokers was observed, our smoking prevention trial demonstrated no significant effect of the intervention.

1. Introduction

In Germany, smoking prevalence among adolescents has dropped substantially over the last two decades, yet more than 7 % of German adolescents still smoke [1]. Schools provide an ideal setting for smoking prevention [2]; however, the most recent update of a Cochrane analysis on school-based smoking prevention programs concluded a lack of long-term effectiveness [3,4].

Face-aging desktop programs, which alter user images to predict their future appearance, have shown promise as prevention tools [6,7]. Considering the importance that adolescents place on appearance [8,9], we developed Smokerface, a program that captures photos of participants' faces and digitally ages them according to a specified level of tobacco consumption. A first randomized controlled trial (RCT) implemented a computer-based version of Smokerface in the secondary school setting as a part of an intervention [10] provided by Education against Tobacco (EAT), a global network of medical students volunteering to deliver school-based smoking prevention [5]. While no significant effect of the intervention was found over 12 months, smoking prevalence after 12 months was numerically lower in the intervention group (IG) than in the control group (CG) (5.8 % vs. 7.2 %), indicating the concept's potential.

Building on these encouraging results and the increasing availability of smartphones, we developed the Smokerface smartphone app in 2015 [11]. This app digitally ages user's 3D self-portrait photos into animated versions that are 1 to 15 years older, models smoking-associated effects on premature aging and skin health, and explains these effects to the user. Since its launch, the free Smokerface app has been downloaded more than 500,000 times and has been translated into the world's most widely spoken languages. A recent RCT by the EAT group in Brazil evaluated the Smokerface app in their school-based curriculum, and demonstrated significantly lower smoking rates in the IG than in the CG after 12 months [12].

Here, we present results of a cluster-RCT, in which the Smokerface app was employed as part of the current EAT curriculum in German schools, aiming to prevent smoking in 6th and 7th grade pupils (12–14 years old).

2. Methods

2.1. Study design

The trial was conducted at German secondary schools from September 2016 to February 2020. The study protocol was pre-registered (ClinicalTrials.gov: NCT02697409) and published alongside process evaluation data [13]. The study was approved by the ethics committee of the University of Giessen and the Ministries of Cultural Affairs of the five participating federal states. Written informed consent was obtained from participants and their parents.

Details on the study design and concept can be found in the study protocol [13]. In brief, we conducted a multicenter cluster-RCT with two parallel groups. Surveys were administered prior to randomization (baseline), and at 9, 16 and 24 months post-intervention. These involved paper & pencil questionnaires distributed and collected through teachers.

2.2. Participants

Pupils attending 7th grade at regular secondary schools in Germany were eligible. Schools that had previously participated in an EAT event were not eligible.

Secondary schools from five German federal states across Southern, Central and Northern Germany (Baden-Wuerttemberg, Bavaria, Hesse, Lower Saxony, North Rhine-Westphalia) were contacted by medical students from twelve different medical universities. In total, 144 schools agreed to participate.

The analysis included pupils from schools that participated in the baseline and at least one other survey, accounting to 7437 pupils from 356 classes. Contrary to the study protocol, a small proportion of 6th grade-students also participated in the study (3.8 %). Since the intervention is also designed for pupils of this grade, we decided not to exclude them retrospectively.

2.3. Randomization

The randomization at school level was centrally managed and executed by the Coordinating Center for Clinical Trials of the Philipps University Marburg (KKS Marburg) (see Supplementary Material A1 for further details).

2.4. Intervention and control condition

For schools allocated to the IG, the intervention involving the Smokerface app was conducted by trained medical students after the baseline survey. Details on the intervention and its contents are described elsewhere [13], and a brief description is provided in Supplementary Material A2. The CG did not receive the intervention and only participated in the surveys.

2.5. Outcomes

The primary endpoint was defined as the between-group difference in cigarette smoking prevalence from baseline to 24 months follow-up. Pupils were classified as smokers if they reported any amount of cigarette smoking during the 30 days preceding the survey.

Secondary outcomes included between-group differences in change in smoking-related intentions and attitudes in accordance with the theory of planned behavior [14], and in changes in smoking behavior (smoking initiation and smoking cessation) after 24 months.

Regarding smoking intentions, pupils were categorized according to their motivational stage following the four-stage model of adolescent smoking initiation [14]. Details on the categorization of the response options can be found in Supplementary Material A3. Briefly, responses were dichotomized into (pre-)contemplaters vs. committers, i.e. those who indicated that they intended to start smoking in the future and those who indicated that they never intended to start smoking, respectively. Pupils who indicated that they were already smoking were excluded.

Regarding attitudes, pupils were asked to indicate their agreement with seven statements about daily smoking ("smoking daily is…": "pleasant", "harmless", "sensible", "exciting", "innocuous", "healthy", "good") on a four-point-scale. Responses were summed, and the sum score rescaled to range from zero to 21, with higher values indicating more positive attitudes towards daily smoking.

2.6. Statistical analysis

Sample size calculation and methods of analysis were predefined in our previously published protocol [13]. Details on the sample size calculation can be found in Supplementary Material A4. The analyses followed the intention to treat principle, i.e. according to the original allocation. Details on the constitution of the study sample can be found in Supplementary Material A5.

Prevalence of smoking, intentions to smoke and the mean attitudes sum score were reported descriptively by group at all four survey time-points. The change in smoking prevalence was reported at 24 months follow-up.

Generalized mixed models were applied to primary and secondary outcomes, accounting for intra-individual correlation over time (unstructured covariance matrix). School was included as a random effect into the hierarchical model. Details on the model specification can be found in Supplementary Material A6. The allocated group was included as fixed effect. To test for within-group changes over time, time was included as a binary time-varying fixed effect. To test for between-group differences in within-group changes of outcomes over time, a time-by-group interaction term was added to the model as a fixed effect. Effect estimates and corresponding 95 %-confidence intervals (CI) for within-group changes over time and for between-group differences in within-group changes are reported. Effect measures are odds ratios (OR) for binary prevalence outcomes, risk ratios (RR) for incidence outcomes and beta estimates for continuous outcomes.

In line with the study protocol, subgroup analyses of the primary endpoint were performed according to gender and school type. Self-reported gender categories comprised girl and boy. Regarding school type, the highest-tier school type existing in all federal states, grammar schools, were compared against all other regular lower-tiered school types, comprising comprehensive schools and secondary schools.

Statistical analyses were carried out using the software SAS version 9.4 (SAS Institute Inc., Cary, N.C., USA). Statistical tests were two-sided, with an alpha level of 0.05 applied for statistical significance testing.

3. Results

Overall, 144 German secondary schools comprising 11,286 pupils participated in the baseline survey (Figure 1). Out of these schools, 100 (IG: 53, CG: 47) participated both in the baseline and at least one of the follow-up surveys.

The CG comprised 3687 and the IF 3750 pupils (Table 1). Baseline characteristics were well-balanced across groups. Gender distribution was roughly 50 %, and most pupils were 12 or 13 years old and in the 7th grade. About 60 % of pupils attended a grammar school and the majority had parents who were born in Germany. Most pupils did not

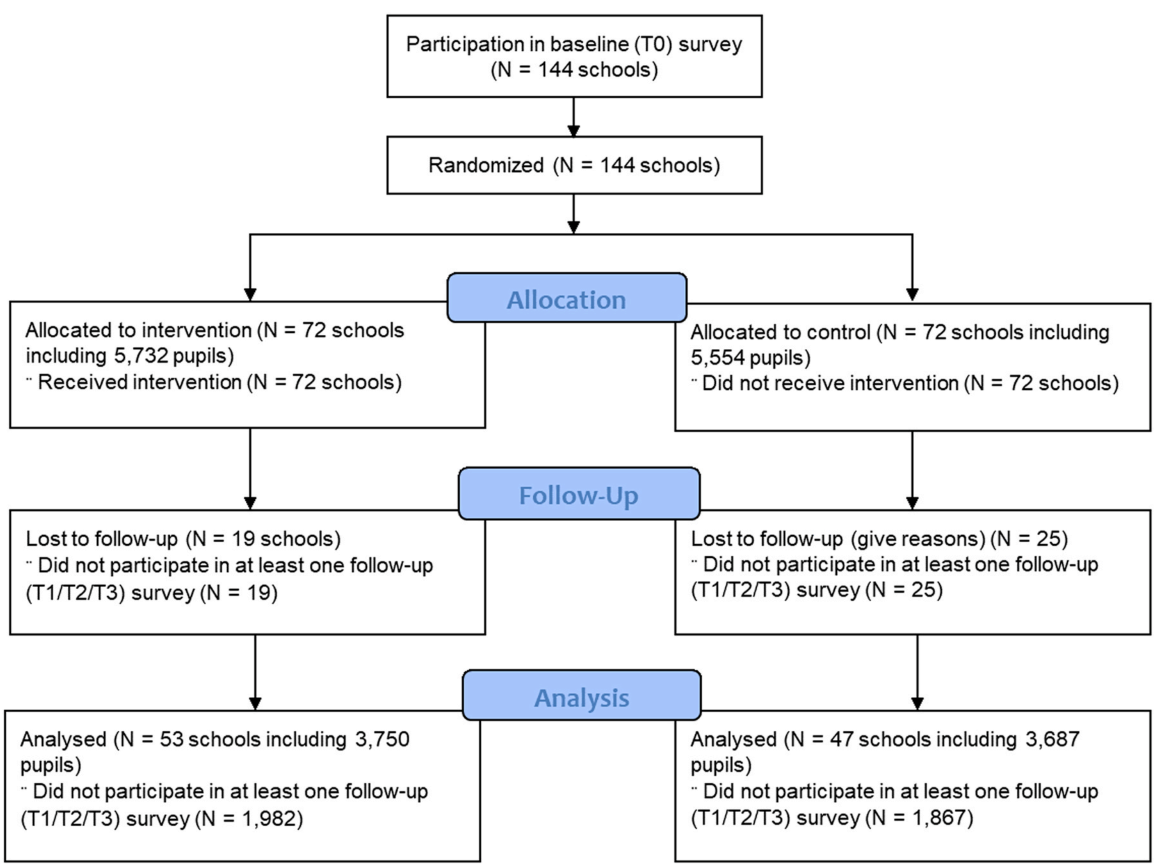

Fig. 1. CONSORT flow diagram of the process of the trial.

Table 1
Baseline characteristics of study participants by group allocation.

	Control Group		Intervention Group	
	N	%	N	%
Total	3687	100	3750	100
Gender				
Girl	1802	48.9	1885	50.3
Boy	1885	51.1	1865	49.7
Age group				
11 years old	37	1.0	114	3.0
12/13 years old	3519	95.4	3455	92.1
14/15/16 years old	131	3.6	181	4.8
Grade				
6th grade	197	5.3	85	2.3
7th grade	3490	94.7	3665	97.7
School type				
Grammar school	2134	57.9	2216	59.1
Other	1553	42.1	1534	40.9
Parents born in Germany				
Both parents	2216	62.7	2301	63.7
One parent	578	16.3	566	15.7
None	743	21.0	745	20.6
Missing	150		138	
Smoking parent				
No	2182	61.4	2191	60.4
Yes	1369	38.6	1439	39.6
Missing	136		120	
Smoking peers (sibling or best friend)				
No	2777	81.2	2792	80.9
Yes	642	18.8	658	19.1
Missing	268		300	
Intention to start smoking (stage of smoking initiation)				
Committer	3352	92.3	3401	91.9
Immotive (pre-contemplator)	145	4.0	150	4.1
Progressive (pre-contemplator)	20	0.6	24	0.7
Contemplator	1	0.0	0	0.0
Smoker	114	3.1	126	3.4
Missing	55		49	
Current smoking				
No	3531	96.9	3580	96.6
Yes	114	3.1	126	3.4
Missing	42		44	

intend to start smoking.

At baseline, only about 3 % of participating pupils were current smokers, with similar rates in both groups (Figure 2). Smoking prevalence gradually increased in both groups over the course of the study, with slightly higher prevalence in the CG at 24 months post-intervention (14.3 % vs. 12.9 %).

Regarding the primary outcome (Table 2), smoking prevalence significantly increased in both groups from baseline to 24 months post-intervention, with an OR= 5.4 (95 %-CI: 4.5–6.5) in the CG and an OR= 4.5 in the IG (3.8–5.4). Although the increase was less pronounced in the IG compared to the CG (OR=0.83, 0.64–1.10), the difference in change between groups did not reach statistical significance.

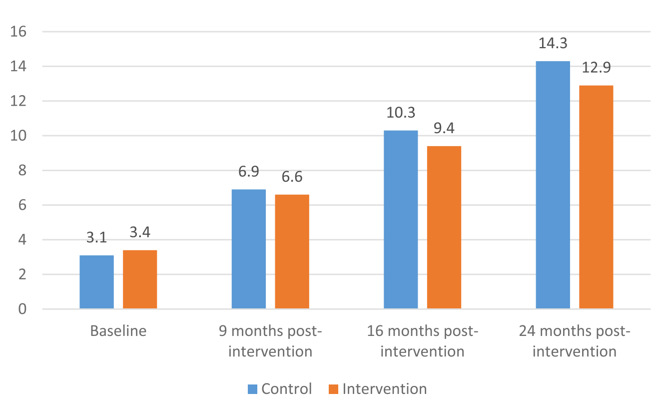

Fig. 2. Prevalence of smoking by group allocation over time.

Table 2
Within-group changes in primary and secondary outcomes over time and between-group differences in within-group changes.

Primary outcome				
Change in smoking prevalence from baseline to 24-months follow-up				
	OR	Lower CI	Upper CI	p-value
Control	5.41	4.47	6.53	< 0.001
Intervention	4.51	3.75	5.41	< 0.001
Intervention vs. Control	0.83	0.64	1.09	0.176
N: 13,584 observations | 7351 subjects				
Secondary outcomes				
Change in prevalence of (pre-)contemplating stage of smoking initiation (baseline non-smokers only) from baseline to 24-months follow-up				
	OR	Lower CI	Upper CI	p-value
Control	0.97	0.77	1.21	0.783
Intervention	0.85	0.68	1.07	0.064
Intervention vs. Control	0.88	0.64	1.21	0.417
N: 12,408 observations | 7193 subjects				
Change in positive attitudes towards smoking from baseline to 24-months follow-up				
	Beta	Lower CI	Upper CI	p-value
Control	0.55	0.41	0.69	< 0.001
Intervention	0.52	0.38	0.66	< 0.001
Intervention vs. Control	0.03	−0.16	0.23	0.734
N: 12,849 observations | 7240 subjects				

Subgroup analysis (Table 3) suggested somewhat greater (though not statistically significant) effects favoring the intervention among boys (OR=0.77, 0.51–1.14) and among pupils from grammar schools (OR=0.74, 0.43–1.26) (Table 3).

Table 4 details changes in smoking status between baseline and 24 months post-intervention. The majority of pupils in both groups remained non-smokers. 12.9 % of pupils in the CG and 11.7 % in the IG started smoking over the follow-up. Both continuous smoking and smoking cessation were rarely observed, and rates did not differ between groups. No significant difference was seen in smoking cessation rates (RR=0.98, 0.63–1.51) among the small subgroup of baseline smokers (details not shown).

When restricting the sample to baseline non-smokers, the incidence of smoking initiation in the CG over 24 months was 13.3 % and 12.1 % in the IG, which yielded a RR of 0.91 (0.69–1.20) for the intervention effect (details not shown). This translates to a number needed to treat of 83.

Table 3
Within-group changes in primary outcome over time and between-group differences in within-group changes by gender and school type subgroups.

Change in smoking prevalence from baseline to 24-months follow-up				
By gender				
	OR	Lower CI	Upper CI	p-value
Girls				
Control	4.86	3.71	6.36	< 0.001
Intervention	4.40	3.37	5.73	< 0.001
Intervention vs. Control	0.91	0.62	1.32	0.605
N: 6784 observations | 3659 subjects				
Boys				
Control	5.96	4.47	7.93	< 0.001
Intervention	4.56	3.46	6.00	< 0.001
Intervention vs. Control	0.77	0.51	1.14	0.186
N: 6800 observations | 3692 subjects				
By school type				
	OR	Lower CI	Upper CI	p-value
Grammar school				
Control	9.97	6.79	14.64	< 0.001
Intervention	7.34	5.06	10.65	< 0.001
Intervention vs. Control	0.74	0.43	1.26	0.262
N: 7970 observations | 4326 subjects				
Other school type				
Control	3.84	3.04	4.84	< 0.001
Intervention	3.57	2.84	4.48	< 0.001
Intervention vs. Control	0.93	0.67	1.29	0.660
N: 5614 observations | 3025 subjects				

Table 4
Changes in smoking status from baseline to 24-months follow-up by allocated group.

	Control N | %	Intervention N | %
Remained non-smoker	2591 | 84.0	2687 | 85.3
Started smoking	397 | 12.9	370 | 11.7
Stopped smoking	52 | 1.7	55 | 1.7
Remained smoker	44 | 1.4	37 | 1.2
Total	3084 | 100	3149 | 100

Approximately 4 % of baseline non-smokers were at the (pre-)contemplating stages of smoking initiation, i.e. reporting an intention to start smoking (Figure 3). In the IG, a non-significant decrease in the prevalence of (pre-)contemplating stage was seen, while no difference between prevalence at baseline and 24 months post-intervention was seen in the CG. The difference in change between groups was not significant (0.88, 0.64–1.21) (Table 2).

Attitudes towards daily smoking were generally negative (Figure 4). Positive attitudes towards smoking increased in both groups to a quite similar extent, and hence no difference between groups in change over time was detected (Beta=0.03, −0.16 to 0.23) (Table 2).

4. Discussion

We conducted a large trial with a comparably long-term follow-up to evaluate the effect of a school-based smoking prevention intervention delivered by medical students, which includes the use of a face-aging mobile app. Although we observed a trend towards a beneficial effect on smoking prevalence over 24 months of follow-up, no significant effect of the intervention could be demonstrated. Regarding motivation to start smoking among non-smokers, no significant difference was found in prevalence of (pre-)contemplating stages, despite a trend favoring the IG. No effect of the intervention on smoking-related attitudes was observed.

The Smokerface app was integrated into the EAT curriculum to capitalize on the high importance that young people place on physical attractiveness [8,9]. It also introduces a more 'game-based' approach to smoking prevention which might be particularly effective in young people who are not very amenable to traditional knowledge and lecture-based interventions. While the use of face-aging technologies has been previously tested in the context of smoking cessation interventions [6,7], to our knowledge, the EAT intervention is the only one to apply such technology in school-based smoking prevention.

Our results align with the main findings of the previous school-based RCT evaluating the implementation of a computer-based Smokerface version as a part of the EAT intervention provided by medical students in Germany [10]. This study found lower smoking prevalence in the IG than in the CG after twelve months (5.8 % vs. 7.2 %), but did not detect statistically significant group differences. However, the previous study was substantially smaller (N = 1504) and hence much less well-powered. A somewhat larger (N = 2348) RCT evaluating a similar EAT intervention involving the Smokerface mobile app conducted in Brazil found significantly lower smoking prevalence twelve months post-intervention in the IG than in the CG (14.1 % vs. 20.9 %) [12].

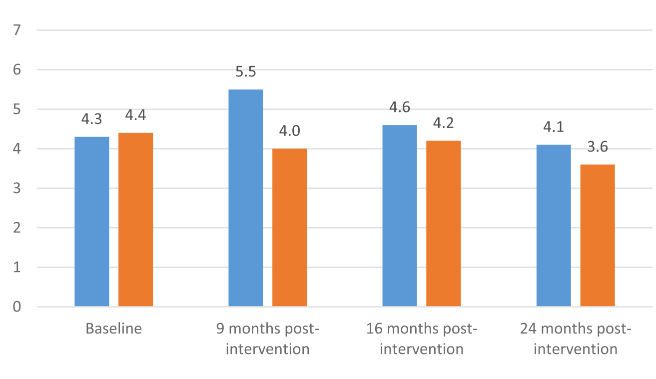

Fig. 3. Prevalence of (pre-)contemplating stage of smoking initiation by group allocation over time (baseline non-smokers only).

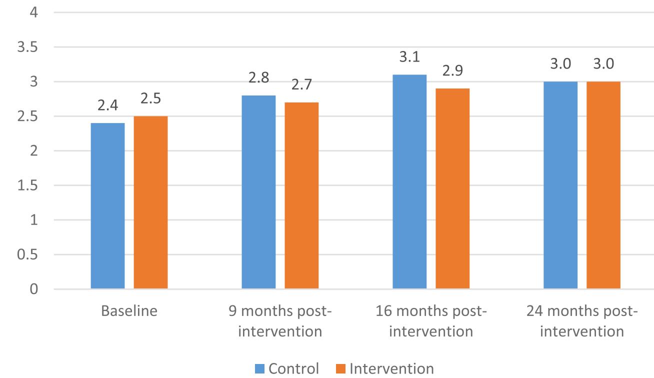

Fig. 4. Positive attitudes towards smoking (mean sum score*) by group allocation over time. * The sum score ranges from zero to 21 with higher values indicating more positive attitudes.

To our knowledge, this present study is the first to investigate intentions to start smoking in relation to a face-aging intervention as a secondary outcome. According to the theory of planned behavior, beliefs (regarding behavior, norms, and behavioral control) shape motivation (intention), which in turn predicts behavior [14]. Although we did not find significant group differences at 24 months post-intervention, we nevertheless observed interesting patterns. While the decreases seen in both groups could partly be explained through self-selection, with those at higher motivational stages actually initiating smoking, the lack of an increase in the IG as opposed to the CG could possibly be attributed to the intervention.

The most recent meta-analysis on school-based smoking prevention among adolescents suggested an overall significant, but limited, effect at longest follow-up, with an average 12 % reduction in starting smoking [4]. In line with this meta-analysis, our study suggested a reduction in smoking initiation of 9 % (albeit not statistically significant). According to this meta-analysis, the only individual curricula types that demonstrated a statistically significant result were those involving social competence curricula. Future versions of the EAT curriculum should integrate such elements. Furthermore, while schools provide a convenient setting for smoking interventions, more comprehensive programs designed to specifically target adolescents' personal environments to enable them to become or remain nonsmokers might be required [16, 17]. This is in accordance with the results of a recent study indicating that the influence of smoking friends reduced the beneficial impact of an interactive smoking prevention intervention [18].

The risk reduction observed in this trial translates to a number needed to treat of 83, which is clearly higher than our pre-defined threshold of clinical significance (NNT=50) [13]. However, the program would likely still be cost-effective given the enormous costs related to smoking and smoking-associated disease [19]. A cost-effectiveness assessment would also have to consider secondary effects on the medical students involved in EAT: participation raises awareness among prospective physicians and trains them in delivering prevention messages [5]. Nevertheless, it remains to be explored how the effectiveness of the prevention program can be improved. Participatory approaches might help in guiding development of interventions and mobile apps that engage adolescents over a longer time.

4.1. Limitations

Over two years, 35 % of schools in the CG and 26 % of schools in the IG were lost to follow-up. At the individual level, the attrition rate was 34 % in the CG and 35 % in the IG. This is a moderate attrition rate for a school-based study over 24 months. As we generally found little differences in distributions of baseline characteristics, we do not expect sample attrition to bias our findings. The attrition has, however, decreased statistical power and hence our ability to detect statistical differences between groups.

Smoking status was based on self-report and was not biochemically validated, and hence might be subject to social desirability bias, particularly in the IG. While this might have led to an overestimation of the intervention effect, a biochemical validation of smoking status on the other hand would have required informed consent to biosample obtainment, thus increasing the risk of selection bias.

We cannot rule out contamination of the CG, which might have led to an underestimation of the intervention effect. The Smokerface app is freely available and pupils in the CG might have downloaded and used it unprompted. Furthermore, schools of the CG might have participated in other school-based smoking interventions, such as the smoke-free class competition, which, however, has been found ineffective in preventing smoking [20].

Finally, only schools from five federal states were recruited, which limits the generalizability of our results.

5. Conclusion

While we observed a trend toward a beneficial effect regarding the primary outcome of smoking prevalence, as well as the secondary outcome of intention to start smoking among baseline non-smokers, no significant effect of the intervention could be demonstrated in our smoking prevention trial.

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Declaration of Competing Interest

TJB programmed the Smokerface App and is therefore formally the owner/rights holder. In 2017, he was offered and accepted 500 Euro per year from another German tobacco prevention charity (ginko Stiftung für Prävention, Germany) to license the Smokerface App for their school-based prevention efforts,with no influence to this study. TJB is also the owner of Smart Health Heidelberg GmbH, a software company which develops digital utehealth apps. Werner Seeger received consulting fees from United Therapeutics, Tiakis Biotech AG, Liquidia, Pieris Pharmaceuticals, Abivax, Pfizer, Medspray BV, outside the submitted work. The other authors declare no conflict of interest.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ejca.2024.114255.

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