Original investigation

The Short-term Effects of ASPIRA: A Web-based, Multimedia Smoking Prevention Program for Adolescents in Romania: A Cluster Randomized Trial

Valentin Nădășan PhD¹, Kristie L. Foley PhD², Melinda Pénzes PhD³, Edit Paulik PhD⁴, Ștefan Mihăicuță PhD⁵, Zoltán Ábrám PhD¹, Jozsef Bálint MD¹, Monika Csibi PhD¹, Robert Urbán PhD⁶

¹Department of Hygiene, University of Medicine and Pharmacy Tîrgu Mureș, Tîrgu Mureș, Romania; ²Social Sciences and Health Policy, Cancer Prevention and Control, Wake Forest University Medical School, Medical Center Blvd., Winston-Salem, NC; ³Institute of Public Health, Faculty of Medicine, Semmelweis University, Budapest, Hungary; ⁴Department of Public Health, Faculty of Medicine, University of Szeged, Szeged, Hungary; ⁵Department of Pulmonology, University of Medicine and Pharmacy, Timișoara, Romania; ⁶Institute of Psychology, Eötvös Loránd University, Budapest, Budapest, Hungary

Corresponding Author: Valentin Nădășan, PhD, Department of Hygiene, University of Medicine and Pharmacy Tîrgu Mureș, 38 Gheorghe Marinescu Street, Tîrgu Mureș 540139, Romania. Telephone: 40-265-215551; Fax: 40-265-210407; E-mail: valentin.nadasan@umftgm.ro

Abstract

Introduction: Although web-based, multimedia smoking prevention programs have been tested in several high-income countries, their efficacy in Central and Eastern Europe is unknown. The aim of this trial was to assess the short-term effects of ASPIRA, among Romanian and Hungarian speaking ninth graders in Tîrgu Mureș, Romania. ASPIRA is the Romanian acronym for the translated and adapted version of ASPIRE, “A Smoking Prevention Interactive Experience,” an evidence-based smoking prevention program originally developed to prevent tobacco use among high school students in the United States.

Methods: Sixteen high schools in Tîrgu Mureș, Romania were randomized to receive five weekly sessions of the ASPIRA web-based, multimedia program or to a control condition. Socio-demographic data, psychosocial characteristics, and smoking behavior were collected from students at baseline and at 6 months. A hierarchical logistic regression analysis was conducted to test the efficacy of the intervention on smoking initiation and current smoking among 1369 students.

Results: Never-smoker students in the intervention arm were 35% less likely to report smoking initiation 6 months after the baseline assessment (OR = 0.65, 95%CI: 0.44–0.97). Reduced smoking initiation was observed most notably among students who were exposed to at least 75% of the ASPIRA program. There was no statistically significant effect of the intervention on current tobacco use (OR = 0.80, 95%CI: 0.44–1.46).

Conclusions: ASPIRA, an adapted version of the evidence-based, multimedia ASPIRE program that was originally developed and tested in the United States may decrease smoking initiation among multi-ethnic adolescents in Central and Eastern Europe.

Implications: (1). Web-based, multimedia smoking prevention programs may be effective tools to prevent smoking initiation among multi-ethnic adolescent communities in Central and Eastern Europe. (2). The degree of exposure is critical, only high exposure to the multimedia smoking prevention program is associated with reduced smoking initiation.
Introduction

Smoking causes more than 5 million deaths worldwide each year, and current trends show that tobacco use will result in more than 8 million deaths annually by the year 2030. While smoking is harmful to people of all ages, children, and adolescents are especially vulnerable to initiation and subsequent short- and long-term consequences of tobacco exposure. It is estimated that 82,000–99,000 young people initiate smoking every day, with the majority residing in low- or middle-income countries. The latest Global Youth Tobacco Survey data from Central and Eastern European countries neighboring Romania report a lifetime smoking prevalence that spans from 39.2% in the Republic of Moldova to 58.8% in Bulgaria and a past 30-day smoking that ranges from 9.3% in Serbia to 28.2% in Bulgaria with a downward time trend over the past 5- to 6-year period. However, the 2011 European School Survey Project on Alcohol and Other Drugs that includes nationally representative data from the same countries suggests that both lifetime and past 30 days smoking prevalence could be higher than estimated in the Global Youth Tobacco Survey. The 2009 Global Youth Tobacco Survey indicates that 41.2% of Romanian school students aged 13–15 years have smoked at least once in their lifetime and 13.5% have smoked at least one cigarette in the past 30 days. The European School Survey Project on Alcohol and Other Drugs 2011 Report shows that lifetime smoking prevalence among 15- to 16-year-old Romanian students could be as high as 52% and last 30 days smoking as high as 29%. A recently published study about 15-year-old adolescents living in Târgu Mureș, Romania reports similar prevalence data (53.2% and 24.1% respectively). Daily smoking rates among 15-year-old Romanian adolescents are estimated between 6.4% and 12%. Comprehensive, evidence-based tobacco control strategies implemented according to the principles outlined in the WHO Framework Convention on Tobacco Control, such as the National Truth Campaign, are needed to reduce the global burden of tobacco. A key element of these strategies is the need for coordinated state and community interventions aimed at preventing youth and young adults from tobacco use initiation.

School-based programs are generally accepted component of a comprehensive strategy to curb tobacco use among children and adolescents. Schools are considered an optimal site for delivering antitobacco programs to children and adolescents, with health education curriculum taught by teachers or trained professionals being the most widely accepted and used intervention in antitobacco education.

School-based interventions may include at least three practical approaches: (1) health education curricula (teachers, health professionals, psychologists and more recently, computers deliver a planned tobacco curriculum over several sessions); (2) peer-based interventions (older student-led interactive educational activities); (3) school policy and culture (setting up tobacco control rules and penalties).

The most comprehensive and recent Cochrane review on the evidence regarding school-based interventions for smoking prevention has shown that their effectiveness varies depending on the type of interventions and the timeframe of the assessment. The pooled analysis of the school-based smoking prevention programs has shown no significant effect on smoking initiation at 1 year follow-up or less, while on the longest follow-up has produced a significant effect. Further subgroup analyses of the interventions at 1-year follow-up or less by type of curricula involved in the program indicated that exclusively information giving and exclusively social influence curricula had no significant effect on smoking initiation, while combined social competence and social influence programs significantly reduced it. Furthermore, social competence-only curricula as well as combined social competence and social influence curricula had significant effects on reducing uptake of smoking while information giving only and social influence only type of curricula have shown no significant effect at the longest follow-up. Finally, no significant effect was detected either at 1 year and longer follow-up for multimodal programs. The mixed results of previous research indicated the need for further investigation on the impact of new technologies in prevention programs.

Web-based programs can be delivered to large groups of adolescents under relatively private conditions. In addition, these programs can be completed at a speed that is convenient to each user, and experts consider that web-based interventions have low-cost. Several web-based programs were developed and tested for their efficacy in various countries including Australia (Consider This), United States (ASPIRE—A Smoking Prevention Interactive Experience), Netherlands (Smoke Alert), Fun without Smokes, Buller et al. reported a significant reduction in last 30 days cigarette smoking among Australian adolescents using “Consider This.” Prokhorov et al., who measured the effects of the original ASPIRE among adolescents in the United States, reported significantly lower smoking initiation rates at 18-month follow-up. In the Netherlands, the authors of “Smoke Alert,” found significantly reduced smoking initiation in the 14- to 16-year age group. The “Fun without Smokes” program had no effect on modifying 10-year-old children’s smoking intentions and behavior. However we are unaware of any similar program in Central and Eastern Europe, despite high rates of tobacco initiation among youth.

ASPIRE is a web-based, multimedia smoking prevention and cessation program addressed to middle and high school students from diverse cultural backgrounds. ASPIRE is a Research-tested Intervention Program which means that the program has produced positive behavioral or psychosocial outcomes, the evidence of outcomes was demonstrated in at least one study conducted within the last 10 years, using an experimental or quasi-experimental design, and was published in a peer-reviewed journal. The efficacy of ASPIRE was tested on a sample of 1574 10th grade students from Houston, United States. The rate of smoking initiation among baseline nonsmoker participants measured at 18-month follow-up was significantly lower in the intervention group compared to the control group (1.9% vs. 5.8%, \( p < .05 \)). Minnesota Smoking Index scores were also significantly lower in the intervention group. Moreover, the students in the intervention group scored significantly favorable on two of the secondary outcomes (decisional balance and temptations to smoke scale) measured at 18 months. Evaluation of the impact of the program on quitters was not possible due to the small number of smokers in the sample.

The current ASPIRA trial (the acronym of the Romanian/Hungarian adapted version of the original ASPIRE was derived from the Romanian name of the trial: “Activitate Şcolară de Prevenire Interactivă a fumatului în România,” which basically conveys the same meaning as the original full name of the ASPIRE program) aims to assess the short-term effects of the translated and adapted web-based, multimedia ASPIRE smoking prevention program on smoking behavior among ninth grade Romanian and Hungarian speaking students in Târgu Mureș, Romania and to test whether the
intensity of exposure to the intervention content is associated with intervention efficacy.

Methods
Design and Participants
This school-based, cluster randomized controlled trial was designed to test the efficacy of ASPIRA to prevent the initiation of smoking among adolescents. The sampling frame included all the 16 high schools in Tirgu Mures, Romania, with a total of 82 ninth grade classes. Inclusion criteria were (1) schools having at least one ninth grade class per school and at least 15 students per class; (2) a functional IT laboratory; and (3) a willingness by the school principal to participate in the study. The list of eligible schools was obtained by the research assistant from the county educational department. Three classes from one school declined to participate due to organizational reasons. The remaining sample included 16 schools, 79 classes, and 2002 students.

In order to minimize contamination, the randomization occurred at the school level with an allocation to treatment and control conditions 1:1. After attaching a two digit code to each of the eligible schools listed in alphabetical order, a concealed random allocation was performed at school level by drawing the school codes written on pieces of folded paper from a bag. All the students in the enrolled schools were invited to participate in the trial.

Enrollment started in November 2014 following approval by the Institutional Review Board of University of Medicine and Pharmacy of Tirgu Mures and by the head of the county education department. Parents were informed about the purpose, benefits, and risks of the study and all parents provided written consent before randomization. Adolescents were included if the following criteria were met: basic computer skills, ninth grade student, and parental written consent.

Students in both conditions completed the baseline questionnaire in November 2014 (1 week before intervention) and the follow-up questionnaire in May 2015 (6 months after baseline, 5 months from the completion of the intervention, 1 week after the booster session). The web-based questionnaire was completed in the computer lab during one teaching hour under the supervision of trained field assistants unknown to the participants. Neither teachers nor school staff was present in the classrooms during the evaluations. Students in the intervention group received five sessions of web-based, multimedia smoking prevention education while students in the control group received no educational intervention.

The flowchart in Figure 1 shows the number of schools, classes, and students at enrollment, at allocation, and follow-up evaluation consistent with Consort 2010 guidelines.24 Students who had inconsistent responses that could not be validated were excluded from the analytical sample (intervention group: n = 4 students at baseline evaluation, n = 51 students at follow-up evaluation; control group: n = 12 students at baseline evaluation, n = 24 students at follow-up evaluation).

Measures
Socio-demographic data were collected on age, sex, and academic achievement (average grades were dichotomized into high grades—7 to 10/low grades—less than 7), and ethnicity (Romanian, Hungarian, Roma, German or other). For analysis, ethnicity was coded as Romanian/non-Romanian (Hungarians, Roma, Germans and other).

Figure 1. Flow diagram of progress of clusters and individuals through phases of ASPIRA trial.
Social influence was measured by perceived peer smoking ("How many of your friends smoke cigarettes?"). Response options ranging from "none" to "all of them" were collapsed into more than half/less than half.

Cigarette smoking was measured by two questions: 1) "Have you ever tried smoking (even one or two puffs)?" (yes/no); and 2) "On how many of the last 30 days have you smoked cigarettes?" (seven categories from none to daily). Participants were categorized as (1) never-smokers ("No" to the first question and "Not smoked in the last 30 days" to the second question), (2) experimenters/non-current smokers ("Yes" to the first question and "Not smoked in the last 30 days" to the second question) or (3) current smokers ("Yes" to the first question and any response other than "Not smoked in the last 30 days" to the second question).

Psychosocial factors were measured by using the 8-item Brief Sensation Seeking Scale24; the 20-item Center for Epidemiological Studies Depression Scale25, which assesses frequency of depressive symptoms and has been validated in Romania; and the Decisional Balance Scale26 which consists of three subscales: coping pros (eg, smoking cigarettes relieves tension), social pros (eg, kids who smoke have more friends), and the cons subscale (eg, smoking cigarettes is hazardous to people's health).

Intention to try smoking during the next year was measured using the question: "At any time during the next year do you think you will try smoking a cigarette?". Response options ("Definitely yes," "Probably yes," "Probably not" and "Definitely not") were collapsed for analysis into two categories ("Definitely not"/all other responses).

The degree of intervention exposure was monitored using data automatically saved on the system server about the progress of participants in the intervention group through the ASPIRA program, and was measured by calculating the percentage of the ASPIRA content viewed by the participants. Students were classified into three categories: high exposure (watched 75%–100% of the content); moderate exposure (watched 25%–74.9% of the content); and low exposure (watched less than 25% of the content).

Intervention Description

The intervention consisted of the translated and adapted version of ASPIRE. ASPIRE was designed for middle and high school students and was developed by the MD Anderson Cancer Center and the University of Texas Health Science Center at Houston.27 The program was designed using the social cognitive theory28 and the transtheoretical model of change29 and contains embedded animations, video, and interactive activities (quizzes and games) structured in five learning modules. The educational content covered the basics regarding smoking prevention and cessation: individual and social determinants of smoking, health, and financial consequences of smoking, nicotine addiction, the impact of smoking on the environment, strategies, and techniques to quit and resist smoking, dealing with stress, peer pressure, social temptations, and mood changes.30

All users received the same content and all modules were presented sequentially; the web material was not tailored per individual's responses and it was not possible to skip modules. Details about the key intervention components by module, step, and media type are presented in the Supplementary Table S1).

During November–December 2014, the students in the intervention group received five weekly sessions of ASPIRA and one “booster” session during the following semester, in May 2015. Each session was 45 to 50 minutes in duration. The ASPIRA field assistants provided the students with general guidance at the beginning of each session and offered individual help at request during the sessions. Students were provided with headphones for privacy and noise reduction and accessed the ASPIRA program individually in the computer lab using unique login codes. Their progress was quantitatively assessed weekly at individual, class and school level. The web-based educational content was available from a subdomain of the University’s website.

Program Translation and Adaptation

The ASPIRE program adaptation process included consultations with Romanian and Hungarian specialists in smoking prevention, with Alexander Prokhorov—the designer of the original ASPIRE, and a feedback received through a formal pilot study that involved prospective participants. The aim of the pilot study was to identify any language, cultural, technical, and implementation barriers in the target group and included a total of 120 Romanian and Hungarian high school and university students.31 Adaptations included: program interface, menu labels, text subtitles, and audio tracks were translated from English into Romanian and Hungarian in order to maximize comprehension of the curriculum; smoking-related statistics referring exclusively to the United States in the original material were replaced with corresponding national or European data; smoking costs expressed in US currency were recalculated in local currency; a number of idiomatic, culturally specific phrases and everyday life situations were substituted with locally meaningful messages or symbols (ie, motivational messages that supposed a detailed understanding of baseball technicalities were transposed in the context of soccer game). Finally, some media content was edited for shortness and a few excluded being considered not relevant in the Romanian context (ie, the Rogue Gallery game, a media material presenting snuff and chewing tobacco, was excluded because their use in Romanian teenagers is extremely low). All changes were approved by the original ASPIRE program staff to ensure the content remained theoretically coherent following cultural adaptations.

Data Analysis

We tested the efficacy of the adapted ASPIRA intervention on smoking initiation (among never-smokers at baseline) and current smoking (among those who previously experimented with tobacco, but were not current smokers at baseline), 6 months after the baseline data collection. We applied hierarchical logistic regression analyses, first introducing the intervention, followed by covariates including demographic characteristics, peer smoking, sensation seeking, and depressive symptoms. In addition, we estimated the effect of intervention dose (defined as exposure to 75% or greater of ASPIRA content or <75% of the content) on the two smoking outcomes. Finally, we estimated the impact of the intervention on potential mediating cognitive variables—decisional balance, negative consequences, and social benefit—by comparing the mean changes in these constructs before and after the intervention, stratified by study arm, using three mixed ANOVA analyses.

All analyses were performed with controlling for the design effect due to the cluster sampling using complex sample analyses in SPSS 21.0. For baseline comparison of control and intervention groups, we applied student t test or Chi-square test for continuous and categorical variables, respectively. A p value of less than .05 was considered statistically significant.
Results

Characteristics of the Sample

The sample included 1369 students in the ninth grade, of which 662 (48.4%) had ever tried smoking and 293 (21.4%) were current smokers. There were differences in baseline characteristics (Table 1), including disproportionately more females in the control versus intervention conditions (59.9% vs. 48.6%, p < .001). Likewise, more students in the control versus intervention conditions reported ever smoking prior to baseline (52.4% vs. 44.1%, p < .002). Students in the control condition were also more likely to report an intention to try smoking within the next year compared to students in the intervention condition (33.6% vs. 26.8%, p < .047). These differences were no longer statistically significant after controlling for clustering. Other characteristics, such as ethnicity, academic achievement, peer smoking, depressive symptoms, sensation seeking, and current smoking were probabilistically equivalent at baseline.

Evaluation of Attrition

Significantly more students in the intervention group were lost-to-follow-up (χ² = 23.1, p < .001); 299 (30.7%) students in the intervention group and 183 (20.9%) in the control group. Therefore, we analyzed the possible attrition bias during the follow-up separately in the two groups. The detailed analyses are presented in Supplementary Tables S2 and S3. Differences in lost to follow-up by treatment arm include: intervention arm participants lost to follow-up were more likely to be ever smokers (65.2% vs. 44.1%), more likely to be current smokers (32.1% vs. 20.0%), and more likely to report having more friends who smoke cigarettes (39.1% vs. 29.5%). Control arm participants who were lost to follow-up were more likely Romanian versus Hungarian (59.0% vs. 50.0%), and more likely current smokers (32.2% vs. 22.7%).

Impact of ASPIRA on the Primary Outcomes: Smoking Initiation and Current Smoking

The behavioral impact of the intervention is presented in Table 2, section A. Never-smoker students who attended intervention schools were 35% less likely to report smoking initiation 6 months after the baseline assessment (OR = 0.65, 95%CI: 0.44–0.97, statistical power = 0.98). The effect remained robust after controlling for gender, age, ethnicity, peer smoking, sensation seeking, and depressive symptoms (OR = 0.66, 95% CI: 0.41–1.04), although no longer statistically significant at p < .05. The experimenter/non-current smoker participants in the intervention arm at baseline were no more or less likely to be current smokers compared to the participants in the control condition, in unadjusted and adjusted analyses. The post hoc power analysis of unadjusted OR = 0.80 revealed that the design was not sufficiently powered to detect the effect (statistical power = 0.44).

The Impact of Intervention Intensity on Primary Outcomes

Intervention exposure was measured by the percentage of the ASPIRA content viewed by the participants. 461 students (68.3%) were exposed to 75% or more of the content which shows that the students in the intervention group were interested in the intervention. Only 20 students (3.0%) were exposed to less than 25% of the content. The binary logistic regression analyses showed that individuals in the high-intensity exposure were significantly less likely to initiate smoking than those in the control condition (OR = 0.62, 95% CI: 0.40–0.98). After adjusting for all covariates the effect size remains the same (OR = 0.62, 95% CI: 0.38–1.05). In addition, those receiving the highest intervention exposure were about half as likely to be current smokers at follow-up (OR = 0.56, 95% CI: 0.30–0.97). While the effect size remained the same after controlling for all covariates, the relationship was no longer statistically significant at p < .05 (OR = 0.56, 95% CI: 0.30–1.05). Lower than 75% exposure was not associated with reduction in initiation or current smoking in the unadjusted and adjusted models (Table 2, section B).

Table 1. Baseline Comparison of Control and Intervention Groups

| Variable                              | Control (N = 694) | Intervention (N = 675) | p     | p*   | Effect size a |
|---------------------------------------|------------------|------------------------|-------|------|---------------|
| Age: mean (SD)                        | 14.89 (0.48)     | 14.87 (0.48)           | .562  | .778 | 0.02          |
| Gender: n (%)                         |                  |                        |       |      |               |
| Female                                | 416 (59.9)       | 328 (48.6)             | <.001 | .162 | 0.11          |
| Male                                  | 278 (40.1)       | 347 (51.4)             | .066  | .812 | 0.05          |
| Ethnicity: n (%)                      |                  |                        |       |      |               |
| Romanian                              | 347 (50.0)       | 371 (55.0)             | .66   | .86  | 0.02          |
| Non-Romanian                          | 347 (50.0)       | 304 (45.0)             |       |      |               |
| Academic achievement: n (%)           |                  |                        |       |      |               |
| High grades                           | 507 (73.1)       | 479 (71.0)             | .389  | .866 | 0.02          |
| Low grades                            | 187 (26.9)       | 196 (29.0)             |       |      |               |
| Peer smoking: n (%)                   |                  |                        |       |      |               |
| More than half                        | 146 (21.0)       | 128 (19.0)             | .338  | .540 | 0.03          |
| Less than half                        | 548 (79.0)       | 547 (81.0)             |       |      |               |
| Depressive symptoms: mean (SD)        | 15.03 (9.44)     | 14.53 (10.03)          | .345  | .593 | 0.03          |
| Sensation seeking: mean (SD)          | 26.31 (6.32)     | 26.17 (6.43)           | .686  | .813 | 0.01          |
| Ever smoked (pre-intervention): n (%) |                  |                        |       |      |               |
| Yes                                   | 364 (52.4)       | 298 (44.1)             | .002  | .179 | 0.08          |
| No                                    | 330 (47.6)       | 377 (55.9)             |       |      |               |
| Intention to try smoking next year: n (%) |                  |                        |       |      |               |
| All the other                         | 111 (33.6)       | 101 (26.8)             | .047  | .160 | 0.07          |
| Definitely not                        | 219 (66.4)       | 276 (73.2)             |       |      |               |
| Current smoking (pre-intervention): n (%) |                  |                        |       |      |               |
| Yes                                   | 158 (22.8)       | 135 (20.0)             | .212  | .548 | 0.04          |
| No                                    | 536 (77.2)       | 540 (80.0)             |       |      |               |

SD = standard deviation.

*After controlling for the cluster effect.

aEffect sizes are expressed in r.

*only those who did not try smoking yet (N = 707).
Table 2. Behavioral Impact of the Intervention

| Predictors | Initiation of smoking between baseline and 6-month follow-up among never-smokers at baseline (N = 707)\(^a\) | Current smoking among students who were experimenters/non-current smokers at baseline (N = 369)\(^b\) |
|------------|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
|            | Step 1 OR (95%CI) | Step 2 OR (95%CI) | Step 3 OR (95%CI) | Step 1 OR (95%CI) | Step 2 OR (95%CI) | Step 3 OR (95%CI) |
| **(A)**    |                                                                                                   |                                                                                                   |
| Treatment condition |                                                                                                   |                                                                                                   |
| Intervention     | 0.65\(^{**}\) (0.44-0.97) | 0.67\(^{*}\) (0.44-1.02) | 0.65\(^{**}\) (0.41-1.04) | 0.80 (0.44-1.46) | 0.84 (0.44-1.62) | 0.85 (0.44-1.63) |
| Control         | Ref.                                                                                              | Ref.                                                                                              | Ref.                                                                                             | Ref.                                                                                             | Ref.                                                                                             | Ref.                                                                                             |
| Gender          |                                                                                                   |                                                                                                   |
| Girls           | —                                                                                                  | 1.12 (0.64-1.95)                                                                                   | 1.11 (0.65-1.91)                                                                                   | —                                                                                                  | 1.89\(^{**}\) (1.27-2.80)                                                                                   | 1.91\(^{***}\) (1.23-2.98)                                                                                   |
| Boys            | —                                                                                                  | Ref.                                                                                              | Ref.                                                                                             | —                                                                                                  | Ref.                                                                                             | Ref.                                                                                             |
| Ethnicity       |                                                                                                   |                                                                                                   |
| Romanian        | —                                                                                                  | —                                                                                                  | 0.84 (0.53-1.31)                                                                                   | —                                                                                                  | —                                                                                                  | 1.10 (0.55-2.21)                                                                                   |
| Non-Romanian    | —                                                                                                  | Ref.                                                                                              | Ref.                                                                                             | —                                                                                                  | Ref.                                                                                             | Ref.                                                                                             |
| Perceived peer smoking |                                                                                                   |                                                                                                   |
| 2/3 of the friends | —                                                                                                  | —                                                                                                  | 2.38\(^{***}\) (1.18-4.78)                                                                                   | —                                                                                                  | —                                                                                                  | 1.28 (0.70-2.34)                                                                                   |
| 1/3 of the friends | —                                                                                                  | —                                                                                                  | Ref.                                                                                             | —                                                                                                  | Ref.                                                                                             | Ref.                                                                                             |
| Age             | —                                                                                                  | —                                                                                                  | 0.97 (0.55-1.72)                                                                                   | —                                                                                                  | —                                                                                                  | 1.19 (0.62-2.31)                                                                                   |
| Sensation seeking | —                                                                                                  | —                                                                                                  | 1.06\(^{*}\) (1.02-1.10)                                                                                   | —                                                                                                  | —                                                                                                  | 1.00 (0.95-1.06)                                                                                   |
| Depressive symptoms | —                                                                                                  | —                                                                                                  | 1.01 (0.98-1.04)                                                                                   | —                                                                                                  | —                                                                                                  | 1.00 (0.97-1.03)                                                                                   |
| **(B)**    |                                                                                                   |                                                                                                   |
| Degree of intervention exposure\(^c\) |                                                                                                   |                                                                                                   |
| ≥75.0%         | 0.62\(^{**}\) (0.40-0.98)                                                                 | 0.63 (0.39-1.02)                                                                                   | 0.62 (0.38-1.05)                                                                                   | 0.53\(^{**}\) (0.30-0.97)                                                                                   | 0.55 (0.30-1.01)                                                                                   | 0.56 (0.30-1.05)                                                                                   |
| < 75.0%        | 0.74 (0.46-1.18)                                                                                   | 0.75 (0.46-1.24)                                                                                   | 0.73 (0.43-1.23)                                                                                   | 1.41 (0.58-3.44)                                                                                   | 1.51 (0.60-3.81)                                                                                   | 1.49 (0.59-3.78)                                                                                   |
| No exposure | (Control)                                                                                          | Ref.                                                                                              | Ref.                                                                                             | Ref.                                                                                             | Ref.                                                                                             | Ref.                                                                                             |

CI = confidence interval; OR = odds ratio;
\(^a\)Outcome variable is initiation of smoking. Cluster effect is controlled.
\(^b\)Outcome variable is smoking during the past 30 days. Cluster effect is controlled.
\(^c\)We do not report here the ORs of variables that were controlled in the analyses.
\(^* p < .10; ** p < .05; *** p < .01.

The Impact of ASPIRA on Decisional Balance as a Secondary Outcome

In addition to the behavioral outcomes, we also tested the impact of the intervention on cognitive variables, namely the components of decision balance which might be important mediators of the treatment effect. The means, standard deviations, main and interaction effects are reported in Table 3. We detected a significant main effect only in negative consequences implying a decrease in the reported negative consequences of tobacco use over time. The main effects in coping-reinforcement and social benefit factors remained unchanged from baseline to 6 months. Therefore, there was no indication that the intervention effect was mediated by these cognitive variables.

Discussions

Our study supports that ASPIRA as a web-based multimedia smoking prevention program might be a useful approach to decrease smoking initiation among adolescents in Central and Eastern Europe similarly to other web-based interventions implemented in the United States and Western Europe.\(^{18,20}\) Although an increasing number of studies have evaluated the efficacy of web-based smoking prevention and cessation interventions,\(^{19,22}\) low- and middle-income countries in Central and Eastern Europe have yet to adopt and test their efficacy in reducing tobacco initiation among youth. Moreover, the local adaptation and translation of a web-based prevention program like ASPIRE demonstrate local capacity to utilize evidence-based programs rather than creating home-grown programs that may/may not have any impact on smoking cessation.\(^{19,20}\) With increasing access to computers and mobile technologies in the region,\(^{21}\) the potential to scale-up such an intervention from a regional to a national study is achievable.

Overall, our study has demonstrated that the intervention reduced tobacco initiation, most notably among those students who were exposed to at least 75% of the ASPIRA program content. Usually the degree of exposure of the contents in web-based smoking prevention programs is not reported in relation to the efficacy of the intervention,\(^{22}\) however, some studies reported a relatively low level of exposure.\(^{18}\) Our study highlighted the necessity to measure the content exposure objectively, nonetheless, other indicators might be used also for future research such as time spent on reading and watching materials. Thus, if the ASPIRA will be adopted as a national youth prevention program, efforts should be made by local teachers and administrators to increase exposure of the program among youth. In line with our result, other web-based programs were also successful in decreasing the incidence of smoking initiation in different age groups,\(^{20,21}\) although some studies also reported null results.\(^{19,22}\) Web-based programs might be a useful method to implement in smoking prevention curriculum in adolescence.

However, we did not find an effect of the program on current tobacco use, which is likely due to the low numbers of children who are engaged in past 30 day smoking and ultimately a limitation imposed by an underpowered study design. Similar negative results were reported regarding smoking behaviors elsewhere.\(^{18,22}\)
Table 3. Impact of Intervention on Potential Mediating Cognitive Variables: Decisional Balance—Negative Consequences, Coping-Reinforcement, and Social Benefit

| Decisional balance | Pre-intervention | Post-intervention | Comparisons |
|--------------------|------------------|-------------------|-------------|
|                    | Control          | Intervention      | Control     | Intervention | F (p)       | F (p)       |
| Negative consequences | 3.92 (0.83) | 3.80 (0.89) | 3.69 (0.96) | 3.56 (1.10) | 63.95 (<.001) | 0.06 (.810) |
| Coping-reinforcement | 1.86 (0.77) | 1.84 (0.82) | 1.87 (0.80) | 1.88 (0.82) | 1.15 (.284) | 0.40 (.526) |
| Social benefit      | 1.57 (0.62) | 1.50 (0.62) | 1.58 (0.66) | 1.52 (0.65) | 1.02 (.313) | 0.03 (.861) |

We also tested the potential role of mediating cognitive variables, such as decisional balance, as the perceived consequences of smoking (good and bad) have previously been shown to influence smoking behavior. However, our results showed no significant effect of the intervention on changes in decisional balance, which raises questions about the cognitive pathways through which interventions that deliver information and skills are perceived and integrated into participants’ psychological functioning and ultimately behavior. Although decisional balance is viewed the most important in preparing quitting smoking, it might be less relevant in initiating smoking among young people. Nevertheless, other cognitive variables such as knowledge, smoking outcome expectancies, social norms would be possible mediators of such interventions and should be tested in the future research.

A recent meta-analysis provided evidence that prevention trials combining social competence/social influences curricula have a significant short-term effect on smoking prevention. In addition to the constructs of the transteoretical model, the content of ASPIRA also covers the social competence and social influences approaches, which can explain why the intervention is effective in spite of the fact that decisional balance is not influenced by the intervention.

This study has several limitations that should be acknowledged. First, given the low prevalence of some tobacco use behavior among youth, including current smoking, the study was likely underpowered to evaluate the effect of the intervention on them. Second, the study was conducted in a single city in the Transylvanian region of Romania with an ethnic composition representative of the region (51.9% Romanian, 45.2% Hungarian, and 2.9% Roma and other ethnic minorities). However, the overall ethnic composition of Romania is 89.5% Romanian, 6.6%, Hungarian, and 3.9% all the other ethnic minorities) which raises questions regarding the generalizability of results to other countries within Romania and to other countries. Nevertheless, our study highlighted the feasibility of web-based smoking prevention programs in urban school settings of middle-income countries. Third, the outcome variables were measured only with self-report, therefore we did not have the opportunity to verify the self-report biologically. An American study supported the validity of self-reported current smoking behavior with cotinine measure in adolescents. However we cannot exclude the possibility that some unmeasured factors influence the self-reported smoking behavior in our sample.

Despite these limitations, there are several notable strengths, including the location of the study. The Central and Eastern European region is less researched in terms of smoking prevention. Our study also contributes with an example of adapting an already tested intervention into two other languages.

Supplementary Material
Supplementary data are available at Nicotine & Tobacco Research online.

Funding
Research reported in this publication was supported by the Fogarty International Center and National Cancer Institute of the National Institutes of Health under Award Number (1R01TW009280). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Declaration of Interests
None declared.

Acknowledgments
Alexander V. Prokhorov, MD, PhD, at University of Texas MD Anderson Cancer Center, Houston, TX.

References
1. Eriksen M, Mackay J, Ross H. The Tobacco Atlas. 4th ed. American Cancer Society, World Lung Foundation. 2012. www.tobaccoatlas.org. Accessed July 24, 2016.
2. Hipple B, Landó H, Klein J, Winicoff J. Global teens and tobacco: a review of the globalization of the tobacco epidemic. Curr Probl Pediatr Adolesc Health Care. 2014;41(8):216–230. doi: 10.1016/j.cppeds.2011.02.010
3. Centers for Disease Control and Prevention. Global Tobacco Surveillance System Data (GTSSData). Fact sheets. 2008. http://ncdc.cdc.gov/GTSSData/Ancillary/DataReports.aspx?CAID=1. Accessed July 21, 2016.
4. Hibell B, Gutormsson U, Ahsström S, et al. The 2011 ESPAD Report - Substance Use Among Students in 36 European Countries. 2012. www.espad.org/en/reports-documents/espad-reports/. Accessed July 21, 2016.
5. Irime S, Mireștean IM, Samoși AC, et al. Tobacco use among students from Romania 2004 versus 2009 GYTS Data. Appl Med Inf. 2010;27(4):55–61.
6. Nădășan V, Foley KL, Pénzes M, et al. Use of electronic cigarettes and alternative tobacco products among Romanian adolescents. Int J Public Health. 2016;61(2):199–207. doi:10.1007/s00038-015-0774-8
7. Ministerul S, Romania [Romanian Ministry of Health], Romania - Global Youth Tobacco Survey (GYTS) Fact Sheet. 2004. www.ms.ro/documente/284_580_GYTS_2004.pdf. Accessed April 10, 2014.
8. Crăciun C, Băban A. Exploring smoking in Romanian adolescents: prevalence, predictors and meanings of smoking. Cognition, Brain, Behavior. 2008;12(4):433.
9. Farrelly MC, Nonnemaker J, Davis KC, Hussin A. The influence of the national truth campaign on smoking initiation. Am J Prev Med. 2009;36(5):379–384. doi:10.1016/j.amepre.2009.01.019
10. Farrell MC, Davis KC, Haviland ML, Messeri P, Healon CG. Evidence of a dose-response relationship between truth antismoking ads and youth smoking prevalence. Am J Public Health. 2005;95(3):425–431. doi:10.2105/AJPH.2004.049692
11. Pierce JP, White VM, Emery SL. What public health strategies are needed to reduce smoking initiation? Tob Control. 2012;21(2):258–64. doi:10.1136/tobaccocontrol-2011-050359
12. Centers for Disease Control and Prevention. Best Practices for Comprehensive Tobacco Control Programs—2014. Rockville, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014.
13. U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: USDHHS, Office on Smoking and Health; 2012.
14. Nădășan V, Chirvăuță R, Ștefănescu L, Mihăcuță S. Two 18-months intervention trials for smoking prevention and cessation in children and adolescents. Pneumologica. 2015;64(3):58–62.
15. Thomas RE, McLellan J, Perera R. School-based programmes for preventing smoking. Evid Based Child Health. 2013;8(5):1616–2040.
16. Australian Government Department of Health and Ageing. Youth Tobacco Prevention Literature Review. Eureka Strategic Research. 2005. www. librarian.net/navon/paper/Project_number_3032.pdf?paperid=20258485. Accessed July 21, 2016.
17. Lantz PM, Jacobson PD, Warner KE, et al. Investing in youth tobacco control: a review of smoking prevention and control strategies. Tob Control. 2000;9(1):47–63.
18. Buller DB, Borland R, Woodall WG, et al. Randomized trials on computer-assisted smoking prevention program in adolescents. Health Educ Behav. 2008;35(2):260–281.
19. Prokhorov AV, Kelder SH, Shogeg R, et al. Project aspire: an interactive, multimedia smoking prevention and cessation curriculum for culturally diverse high school students. Subst Use Misuse. 2010;45(6):983–1006.
20. Prokhorov AV, Kelder SH, Shogeg R, et al. Impact of a smoking prevention interactive experience (aspire), an interactive, multimedia smoking prevention and cessation curriculum for culturally diverse high school students. Nicotine Tob Res. 2008;10(9):1477–1485.
21. de Josselin de Jong S, Candel M, Segarra D, Cremers HP, de Vries H. Efficacy of a Web-based computer-tailored smoking prevention intervention for Dutch adolescents: randomized controlled trial. J Med Internet Res. 2014;16(3):e28. doi:10.2196/jmir.2469
22. Cremers HP, Merckel C, Candel M, de Vries H, Oenema A. A Web-based, computer-tailored smoking prevention program to prevent children from starting to smoke after transferring to secondary school: randomized controlled trial. J Med Internet Res. 2015;17(3):e59.
23. National Cancer Institute. Research-tested Intervention Programs (RTIPs). http://rtips.cancer.gov/rtips/index.do. Accessed July 15, 2016.
24. Campbell MK, Paggo G, Elbourne DR, Altman DG. CONSORT Group. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661. doi:10.1136/bmj.e5661
25. Sargent JD, Tanski S, Stooßmüller M, Hanewinkel R. Using sensation seeking to target adolescents for substance use interventions. Addiction. 2010;105(3):506–514.
26. Stevens MJ, Uscătescu L, Butucescu A, Constantinescu PM, Ion BC, Sandu CG. The Romanian CES-D scale: a promising instrument for clinical and non-clinical use. Int J Educ Psychol Commun. 2013;3(2):7–21.
27. Plummer BA, Velicer WF, Redding CA, et al. Stage of change, decisional balance, and temptations for smoking: measurement and validation in a large, school-based population of adolescents. Addict Behav. 2001;26(4):551–571.
28. National Cancer Institute and Substance Abuse and Mental Health Services Administration. A Smoking Prevention Interactive Experience (ASPIRE) on Research-tested Interventions Programs website. 2015. http://rtips.cancer.gov/rtips/programDetails.do?programId=2440327. Accessed July 4, 2016.
29. Bandura A. Social Foundations of Thought and Action: A Social Cognitive Theory. Englewood Cliffs, NJ: Prentice-Hall; 1986.
30. Prochaska JO, DiClemente CC, Norcross JC. In search of how people change. applications to addictive behaviors. Am Psychol. 1992;47(9):1102–1114.
31. Ștefănescu L, Nădășan V, Bálint I, Ferencz JL. Translation and adaptation of computer assisted smoking prevention program in romania (aspira). Acta Medica Transilvania. 2015;20(3):14–16.
32. European Commission. Special Eurobarometer 414 - E-Communications and Telecom Single Market Household Survey. 2014. doi:10.2759/5615. http://ec.europa.eu/public_opinion/archives/ebss/ebss_414_en.pdf. Accessed July 21, 2016.
33. Velicer WF, DiClemente CC, Prochaska JO, Brandenburg N. Decisional balance measure for assessing and predicting smoking status. J Pers Soc Psychol. 1985;48(5):1279–1289.
34. Redding CA, Prochaska JO, Paiva A, et al. Baseline stage, severity, and effort effects differentiate stable smokers from maintainers and relapers. Subst Use Misuse. 2011;46(13):1664–1674.
35. Gokbayrak NS, Paiva AL, Blissmer BJ, Prochaska JO. Predictors of relapse among smokers: transtheoretical effort variables, demographics, and smoking severity. Addict Behav. 2015;42:176–179.
36. Thomas RE, McLellan J, Perera R. Effectiveness of school-based smoking prevention curricula: systematic review and meta-analysis. BMJ Open. 2015;5(3):e006976.
37. Dolcini MM, Adler NE, Lee P, Baum KE. An assessment of the validity of adolescent self-reported smoking using three biological indicators. Nicotine Tob Res. 2003;5(4):473–483.