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## One-year effects of Project EX: A smoking intervention pilot program with Spanish adolescents

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### Abstract

Adolescent smoking is a major public health problem, which has led to the development of cessation programs such as Project EX. However, there is no evidence for the long-term efficacy of cessation among Spanish adolescents. This study provides a 1-year follow-up evaluation of the Project EX tobacco use cessation program among 211 smokers. The intent-to-treat 30-day smoking quit rate for the program group was 7.81 percent ( $p = .04$ ), whereas no smokers quit in the control group ( $p = .02$ ). The intervention had a significant influence on future smoking expectation, intention, motivation to quit, and overall level of 30-day smoking. Long-term outcomes of the Project EX clinic-based program are promising for adolescent smokers in Spain.

### Keywords

intervention; Project EX; smoking cessation; Spain; tobacco

### Introduction

Adolescent smoking is a major public health problem (Audrain-McGovern et al., 2014), and although youth often hope they will quit soon, the addictive nature of nicotine leads many to continue smoking for decades (Ariza et al., 2014). In western countries, more than half of school children have tried tobacco during high school. In the United States, almost 90 percent of new smokers tried their first cigarette before the age of 18 years (Centers for Disease Control and Prevention (CDC), 2012), and in Europe, 54 percent of 15-year olds have smoked cigarettes at least once in their lifetime, with more than half of lifetime smokers having smoked cigarettes in the last 30 days (Hibell et al., 2012). According to the latest data from the National Drug Plan (Spanish Drugs Observatory, 2013), the prevalence of regular smoking in Spain is 12 percent for boys and 13.1 percent for girls.

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Compared to adult cessation programs, there have been relatively few studies of teen smoking cessation conducted worldwide, and only 25 percent have been conducted outside the United States (Sussman, 2012). In Spain, there is no published evidence for the long-term efficacy of cessation programs among adolescent smokers.

Project EX was developed in the United States (California) and has been selected as an evidence-based program by several national-level health agencies (e.g. National Registry of Evidence-Based Programs and Practices (NREPP)/Substance Abuse and Mental Health Services Administration (SAMHSA), National Cancer Institute (NCI), Health Canada). The program is derived from a theoretical model of smoking in adolescence, which emphasizes the role of motivational factors, personal skills, and coping with withdrawal (Sussman et al., 2004). The results of controlled studies on the Project EX clinic program in the United States were consistently positive. At a 3- to 6-month follow-up, last 30-day quit rate was approximately 17 percent in the program condition, which generally doubled quitting rates compared to the control condition (Sussman, 2012; Sussman et al., 2001, 2004).

In order to evaluate the efficacy of the program in other cultures where motivations for quitting smoking may differ from the United States, the program was implemented and evaluated in several other countries (Sussman, 2012). The first international pilot study completed was in Wuhan, China (Zheng et al., 2004), and the clinic program was evaluated by using a multiple baseline design. The naturally occurring (control group) quit rate was 3 percent, whereas the program condition intent-to-treat 30-day quit rate was 11 percent at a 4-month follow-up. The program was rated as very helpful. The second international pilot study was the Bashkortostan (Russia) study (Idrisov et al., 2013), which presented an intent-to-treat 30-day quit rate of 7.5 percent versus 0.1 percent at a 6-month follow-up. The third international trial of the Project EX school-based clinic program was developed in Spain (Espada et al., 2015). At immediate posttest, Project EX significantly reduced future nicotine dependence scores, increased intention to quit smoking, and led to a higher previous day (prior to assessment) quit rate. At the 6-month follow-up, 14.28 percent had quit smoking in the program group, whereas there were no quitters in the control group. Also, Project EX had a significant influence on future smoking expectation and the overall level of 30-day smoking. This was the first controlled school-based clinic trial of teen tobacco use cessation conducted in Spain, but its long-term efficacy is unknown.

This article focuses on the 1-year self-reported behavioral outcomes of the Project EX cessation program with Spanish adolescents. The variations in sustained use or cessation are observed in the long term (Dijk et al., 2007), so we hypothesized that the program group would show that the effects of the program are maintained in the whole sample at 1-year follow-up, which would bolster the practical importance of its effects in Spain.

## Method

### Recruitment and experimental design

We used a convenience sample of 73 schools from 22 towns in the Southeast of Spain. After the first meeting to present the intervention objectives to the school boards, a total of nine schools (12.3% of the schools approached) reported being willing to participate. The

recruited schools were randomly assigned to one of two experimental conditions: control group and program group. The students in the control group remained on the waiting list. When the program finished in the program group and all evaluations were completed, control group students received the program. There were four schools in program condition and five in control condition.

The reasons for non-recruitment of schools were as follows: no response after a single initial contact (56%), responded back to us after a first meeting with a statement of no staff interest (34%), and no student smokers interested in participating after a visit to the school and an attempt to recruit smokers (10%).

Subject-level inclusion criteria included adolescent cigarette smokers of 13–19 years old, having had a cigarette in the last 30 days at baseline, having joined the clinic in the first 2 of the 6 weeks (on or before Session 4), and reporting to be willing to attend the school-based clinic program. An e-mail address was provided to potential participants so that they might confidentially contact the researcher for further information or to join the program.

### **Project EX curriculum**

The Project EX clinic program involves eight sessions. During the first four sessions, students are prepared to strengthen their resolve to quit tobacco use. The second four sessions are focused on quit-attempts. A more detailed description of the sessions can be found in the previous article on the implementation and immediate outcomes of the project (Espada et al., 2015).

### **Translation and cultural adaptation**

The original version of the curriculum was provided by the Project EX team at the University of Southern California (USC). It was translated into Spanish by two translators, bilingual researchers from the University Miguel Hernández (UMH) Spain, who then checked the translation by reading both the English and Spanish versions. Before the program was implemented, the Spanish version was pilot-tested on a focus group comprising 10 youths at the same university to verify that the program material was clearly understood and culturally appropriate.

In addition to language adaptations, five major changes were made to the curriculum to adapt it to Spanish culture. The first change was related to the incentives provided in Project EX when it was implemented in the United States. In most implementations, students were provided with extrinsic motivators; for example, they were told that they would obtain elective credits for participating in the program (i.e. they did not have to stay after school). In Spain, however, as in other international settings where Project EX is being implemented (Idrisov et al., 2013; Sussman, 2012), no incentives were included for attending the program sessions. Second, the original curriculum targets “tobacco” use which includes smokeless tobacco, pipes, cigars, and chewing tobacco. So, as Spanish adolescents very rarely use any other form of tobacco than cigarettes (Meneses et al., 2013; Spanish Drugs Observatory, 2013), that information was removed and the program focused on cigarette smoking. Third, all names of characters in the talk shows (see Sussman, 2012) were changed from American to Spanish names. Fourth, the monetary amounts were changed from dollars to euros; for

example, in Session 1, regarding the amount of money spent per year from smoking a pack of cigarettes a day. Finally, in Session 3 “Health Dangers of Tobacco Use,” the original curriculum included a question list for a game about second-hand smoke and policies. In this case, questions and forced-choice responses were changed to reflect policies in Spain. For example, one question asks “In which of the following places is it legal to smoke in the United States? (“Airline flight,” “Interstate bus,” “New York City taxi cab,” and “None of the above”).” This item was replaced with “In which of the following places is it legal to smoke in Spain? (“Airport,” “Bus station,” “Taxis,” and “None of the above” [correct answer]).”

## Participants

Participants were 211 students from the South East region of Spain, which has a population of approximately 2 million and an area of more than 5800 km<sup>2</sup>. The sample was a representative percentage of the adolescent Spanish population in percentage for gender and age. Participants were randomly assigned to one of two experimental conditions (99 in the control condition and 112 in the program condition). Participants and their parents provided written informed assent and consent, respectively, to participate in this study. Parents were only told that their children would participate in a study on health promotion, including tobacco education. The assessment was carried out during the first meeting, in small groups (not significant (ns) = 5–10). Among the 211 subjects who participated in the pretest survey, 92 (34 in the control condition and 58 in the program condition) also completed 1-year follow-up questionnaires (43.6% retention rate).

Adolescents in the control condition received no formalized intervention classes, materials, or programs and were surveyed at each time point. Once the program group had received the intervention and all evaluations had been completed, control group students received the program (as a wait-list control).

Participants varied in age from 15 to 20 years ( $M = 17.2$ ; standard deviation ( $SD$ ) = 1.23), at 1-year follow-up. The sample was 48.6 percent male, 93 percent Spanish, and 7 percent other nationality (North Africa, Central Europe, and South America), and 74.6 percent of the students lived with both parents.

## Training in Project EX

The initial 8-hour training was conducted at USC for the Spanish research team in charge of the adaptation of Project EX, to guide the translation, cultural adaptation, and implementation. Then a second training seminar of 8 hours was scheduled for 11 graduate psychology students at the UMH. These students were given the opportunity to become program facilitators. All volunteers received an introductory lecture about Project EX, which included a brief summary of the curriculum, its history, advantages of using the program, and the role of program facilitators. Six graduate students (all females; mean age = 24 years) were interested in implementing the program. These facilitators received extra training during 2-hour meetings, each after studying and practicing the eight Project EX sessions during a 2-day workshop led by the program developer (Dr Steven Sussman) and Project EX

health educator (Daniel Soto, MPH), including learning details of program delivery and how to deliver the material with fidelity.

### **Implementation, data collection, and measures**

The clinic program was delivered in classrooms over a 5-week period after school. For the first 8 weeks, there were two clinic sessions a week, and over the subsequent 2 weeks one session a week. Paper-and-pencil pretest and follow-up questionnaires were administered at the beginning of the first session and 1 year after completion of the eight session programs. This pilot study was approved by the Ethics Committee of Miguel Hernández University, ensuring that the study respects human rights, maximizes confidentiality of the participants' responses, and does not involve risk to participants. Data were collected by the same persons who had delivered the program to specific clinic groups. Data were collected at pretest just prior to Session 1, at 6 months after the last session (Espada et al., 2015), and 1 year after completion of the program (with the same time lag in the control condition). Attempts were made to help maintain confidentiality of the responses by placing completed questionnaires into sealed envelopes, relaying to youth that only the data analyst at UMH would see their responses, and telling them that their data would be entered via a code number rather than by name.

Questionnaires took approximately 20 minutes to complete. Demographic items included age (in years), gender, nationality (born in Spain, or immigrated to Spain from another country), and current living situation (with parents, living alone, other situation). Smoking behavior (past month) was assessed by means of an open-ended question "How many times have you used cigarettes in the last month (30 days)? (0 to 100+ times)," which was the outcome measured at the 1-year follow-up. To assess intention to quit, students were assessed with the question "Do you think you will ever quit smoking cigarettes?" Response categories were as follows: "0: I never smoke cigarettes," "1: Yes, I already have," "2: Yes, I will sometime in the future," "3: Yes, I will in the next few weeks," "4: Maybe," and "5: No." Smoking expectation was assessed with the question "How likely is it that you will smoke cigarettes in the next 12 months?" Response categories were as follows: "0: Definitely not," "1: Probably not," "2: A little likely," "3: Somewhat likely," and "5: Very likely." Motivation to quit was assessed with the question "How much do you want to quit smoking now and/or stay smoke-free?" Response categories were as follows: "1: A lot," "2: Somewhat," "3: Slightly," and "4: Not at all." The level of nicotine dependence was assessed with the eight-item modified Fagerström Tolerance Questionnaire (mFTQ) (Idrisov et al., 2013; Prokhorov et al., 1996, 2000). Nicotine dependence was dichotomized into 0 or low (0–5) and high (6–9) levels.

### **Data analysis**

We used chi-square to analyze attrition. Variables included school, age, gender, program condition, nationality, whether or not participant lives with both parents, last 30-day cigarette smoking, future smoking expectation, intention to quit, motivation to quit, and mFTQ (dichotomized into low and high nicotine dependence). The analysis of attrition was performed across conditions (stayers versus leavers; external invalidity) and regarding the interaction between condition and each one of the related variables (internal validity).

Data analysis for program effects was completed with multi-level mixed analysis, by using the package *nlme* (Pinheiro et al., 2014) from the *R* statistical program. In these analyses, condition was considered as a fixed variable (program group compared to control group), and school was considered as a random factor. With these specifications, we can control for the intra-class correlation (of schools nested within condition) between scores at pretest and follow-up. Variables adjusted for in the analyses included baseline measurements for the outcome variables that were examined in the specific analysis, age, gender, and propensity for attrition at 1-year follow-up. The propensity for attrition score was calculated from a model predicting the actual attrition status with pretest measures (Berger, 2005). The pretest measures in the attrition propensity prediction models included school, age, gender, study condition, nationality, whether or not living with both parents, intention to quit smoking, future smoking expectation, motivation to quit, last 30-day cigarette smoking, and mFTQ for self-reported nicotine dependence level. The outcome variables analyzed were as follows: last 30-day cigarette smoking, future smoking expectation, intention to quit, motivation to quit, and mFTQ scores. Cohen's *d* effect sizes for each variable were calculated. Finally, for the quit analysis, we used the Fisher's exact test without controlling any variable.

## Results

### Assessment of attrition bias at 1-year follow-up

First, the influences of demographic variables and each outcome variable were examined for attrition across conditions (external validity). Two separate analyses were performed, and at 1-year follow-up 119 participants were lost (56.39% attrition). School was found to be significantly different across attrition status ( $p < .001$ ), and last 30-day cigarette smoking was also statistically significant ( $p < .001$ ). Students who dropped out reported an average consumption of 205 cigarettes per month ( $SD = 174$ ) at baseline, while participants who surveyed at 1-year follow-up reported an average consumption of 102 cigarettes per month at baseline ( $SD = 75$ ).

Finally, the attrition analysis for comparing conditions (internal invalidity) was completed. The percentage of subjects at 1-year follow-up who dropped out of the study was similar across conditions ( $\chi^2(1) = 0.1$ ;  $p = .54$ ). At 1-year follow-up, the attrition analysis revealed statistically significant differences across experimental conditions. The program group exhibited 48.21 percent of attrition, whereas the control group exhibited 65.65 percent of attrition ( $\chi^2(1) = 24.11$ ;  $p < .01$ ). However, no significant condition interaction effects were found for demographic or outcome variables.

### Program effects at 1-year follow-up

The 30-day intent-to treat smoking quit rate for each condition was calculated. In the program condition, the percentage of quitters was 7.81 percent (i.e. 10 smokers quit; Fisher's exact test:  $p = .04$ ), and there was no adolescent who stopped smoking in the control group (Fisher's exact test:  $p = .02$ ). Table 1 shows the variability of the dependent variables evaluated for program and control groups. Project EX demonstrated a relatively greater decrease in future smoking expectation ( $d = .73$ ;  $p = .04$ ), elicited greater intention to quit ( $d = .82$ ;  $p = .001$ ), higher motivation to quit ( $d = .34$ ;  $p = .009$ ), lower mFTQ scores ( $d$

= .56;  $p < .05$ ), and greater influence on number of cigarettes in the last 30 days ( $d = .26$ ;  $p < .001$ ; pretest: control mean = 138.2,  $SD = 176.86$ , program mean = 193.11,  $SD = 174.68$ ; follow-up: control mean = 109.12,  $SD = 175.36$ , program mean = 84.21,  $SD = 101.47$ ).

## Discussion

The high rates of teenage smoking in Spain indicate the need to develop effective long-term programs for tobacco cessation such as Project EX, which is derived from a theoretical model of smoking in adolescence. This study tested the 1-year effects of this cessation program among Spanish adolescents.

Participants who received the program reported a statistically significant greater intention to quit. Furthermore, in this study, participants in the program group reported lower scores in future smoking expectation and nicotine dependence, and higher motivation to quit smoking at 1-year follow-up. Furthermore, 18.75 percent quit smoking (no one in the control group quit), compared to the initial number of smokers at pretest. Reduction in the level of 30-day smoking at 1-year follow-up was also significant.

Compared to the results at immediate post-test and the 6-month follow-up, the long-term effects of Project EX are more promising. Participants who received the program experienced an improvement in all variables, with reduced scores in future nicotine dependence scores and increased scores in intention to quit at immediate posttest, and 6-month follow-up showed its influence on future smoking expectation. In a clustered randomized controlled trial, approximately 14 percent quit in the program group versus 0 percent in the control group (Espada et al., 2015). These results indicate that Project EX as a cessation program has the potential long-term effects for smoking cessation among adolescents in Spain.

Considering previous studies on Project EX in other countries, the results in Spain are promising. In China, 4-month follow-up data indicated a 10.5 percent 30-day quit rate and a 14.3 percent 7-day quit rate, compared to a 3 percent naturally occurring quit rate in a multiple baseline design (Zheng et al., 2004). Project EX in Russia (Idrisov et al., 2013) resulted in a 7 percent quit rate at the 6-month follow-up, compared to a 0 percent control group quit rate in a randomized controlled trial. Furthermore, the program significantly reduced intention to quit and future smoking intention and increased motivation to quit smoking at immediate posttest.

Still, there are several major limitations and related needs for future research. First, although our sample is not unlike that of other pilot studies (e.g. Idrisov et al., 2013; Zheng et al., 2004), future research on tobacco use cessation programming in Spain is needed with larger sample sizes and in other regions of the country. It should also include other socioeconomic and cultural variables so as to analyze possible efficacy differences between the original program and the Spanish adaptation to cultural aspects. Also, we do provide an intent-to-treat analysis for cessation, which accounts for attrition, and while we do statistically account for threats to external and internal validity statistically, we do acknowledge the limitations of our sample size. Second, the dropout rate at 1-year follow-up was 56.39

percent. We did make at least three attempts per school to collect 1-year follow-up data, suggesting that higher follow-up rates would be difficult to obtain. Student absentees accounted for most of the non-completion although subject withdrawal from the study accounted for 43 percent of the non-completion of questionnaires at follow-up. In addition, we made five attempts to telephone those students who we could not reach at the schools. Only 7 percent of the calls were answered (93% of the phone numbers were incorrect, were turned off, or were not answered). This dropout rate makes it difficult to wholly know the intervention effect. In order to control this, we have reported intent-to-treat data, assuming that dropouts were still smoking. However, the attrition rate made it difficult to generalize the results. Certainly, there was a lack of general readiness to be involved in cessation programming, indicated by the percentage of schools that agreed to be involved initially, and the groups of young smokers who dropped out before the program even started or after the first session, as well as a rather high attrition rate. Implementation was held after school times, and participants did not receive any material incentive for participating, which may have led to a general lack of readiness on the part of the students. Providing coupon-based incentives can be an effective approach to encouraging positive behavior and is commonly used as response-contingent reinforcement in school. A previous study suggested that appropriate shaping by reinforcing initial attempts to quit can also improve the efficacy of smoking cessation programs for people who are difficult to treat (Lamb et al., 2010). Furthermore, incentives may support student's motivation to quit smoking, as would reward for their efforts when they quit smoking (Cahill and Perera, 2011). Use of coupon-based incentives should be considered to reduce dropout rates in the future. The results were still meaningful, because, as we have already mentioned, we reported intent-to-treat data, assuming that dropouts were still smoking. Third, future trials may be strengthened by the use of biochemical validation of nicotine use, as done in the class version (Espada et al., 2014; González et al., 2015). Finally, future studies might assess the use of other tobacco products in Spain. For example, while almost all tobacco use among adolescents has been cigarette smoking, the marketing of electronic cigarettes has been very aggressive. Besides serving as a gateway to tobacco consumption by adolescents, they can promote stagnation in the process of smoking cessation process (Wills et al., 2015).

Despite the limitations of this study, Project EX is the first evidence-based approach previously evaluated in Spain for adolescent smoking cessation. The results of this study suggest that Project EX can be used as an effective tobacco use intervention for adolescents in Spain, given the maintenance and improvement of its long-term effects.

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Table 1.

One-year follow-up program effects.<sup>a</sup>

	Control (n = 34) 1-year pretest ± SE	Program (n = 58) 1-year pretest ± SE	Net effect 1-year pretest ± SE	d
Future smoking expectation <sup>b</sup>	-0.16 ± 0.12	0.46 ± 0.11**	0.74 ± 0.07*	.73
Intention to quit	-0.49 ± 0.21	0.93 ± 0.15	1.27 ± 0.06***	.82
Motivation to quit <sup>b</sup>	0.09 ± 0.11	0.26 ± 0.13	0.12 ± 0.02**	.34
mFTQ nicotine dependence	0.33 ± 0.14	0.59 ± 0.21*	0.26 ± 0.11*	.56
Number of cigarettes in the last 30 days (active smokers only; n control = 34, n program = 48)	-29.43 ± 112.19	-63.94 ± 113.22**	-34.61 ± 112.91***	.26

SE: standard error; mFTQ: modified Fagerström Tolerance Questionnaire.

<sup>a</sup> Adjusted for the specific outcome assessed at baseline, age, gender, and school for attrition center modeled as a random effect.<sup>b</sup> Reversed score.\*  $p < .05$ , two-tailed;\*\*  $p < .01$ , two-tailed;\*\*\*  $p < .001$ , two-tailed.