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Effectiveness of a complex intervention on smoking in adolescents: A cluster-randomized controlled trial

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ABSTRACT

Tobacco smoking is a major preventable cause of death, and a significant public health problem worldwide. Most smokers begin in adolescence, age at which they are more susceptible to nicotine addiction. The prevalence of smoking in adolescence is considerable. Therefore, it would be convenient to incorporate smoking prevention programs in the school environment. It is necessary to provide evidence of its effectiveness. The primary objective of the study was to evaluate the effectiveness of a teacher-delivered school-based intervention on the initiation of smoking in adolescents (ITACA smoking prevention education program).

A multi-center cluster randomized trial was designed. Twenty-two secondary schools from Spain were enrolled in 2 successive cohorts, from 2010 to 2011. The intervention consisted in the application of the ITACA smoking prevention education program. A 4-year cognitive-behavioral intervention that is based on the social-influences model and is integrated into schools' regular curricular activities. A total of 1055 students were surveyed before the intervention (age: 12–13 years-old), and at the third year of the intervention (age: 14–15 years-old) of a 4-year education program. The outcome measures were daily and weekly use of cigarettes, and initiation of smoking.

There was no evidence that the intervention impacted the incidence of regular smoking (OR = 1.08; 95% CI: 0.50–2.33) or the initiation of smoking (OR = 1.09; 95% CI: 0.56–1.72).

This trial provides evidence supporting the non-effectiveness of a complex educational smoking prevention program at 3 years after the intervention.

Trial registration number: Current Controlled Trials: NCT01602796.

1. Introduction

Most smokers start to smoke in their early teens. An estimated 50% of adolescents who start to smoke continue to smoke for at least 16 to 20 years (Pierce and Gilpin, 1996). Compared with adults, young people are more susceptible to nicotine addiction (Lydon et al., 2014). The WHO Health Behavior in School-aged Children (HBSC) study reported that approximately 12% of 15 year-olds smoke cigarettes at least once a week. In the European Union, the percentage of regular smokers is 6% for 13 year-olds and 18% for 15 year-olds, and the smoking rate of 15-year-olds is similar to that of adults. In Spain, the percentage of regular smokers of 15 years-old adolescents is 23% for girls and 15% for

boys (Currie et al., 2012).

Adolescence is the time of transition to adulthood, and adolescents may engage in risky behaviors while trying to become adults. The emotional, social, and cognitive changes during adolescence make this a time when individuals are more likely to begin tobacco use. Parental smoking (Gilman et al., 2009) and smoking among friends or peers (Hill et al., 2005) has special relevance during this period. However, the causes of smoking by adolescents are complex and some others factors have been described: genetic factors (Li et al., 2003), stress (Lemmas et al., 2015), low self-esteem (Wild et al., 2004), poor locus of control (Bennett et al., 1997), low school perception (Lemmas et al., 2015; Yanez et al., 2013), susceptibility to peer influence (Lavack and Kropp,

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2003), secondhand tobacco smoke exposure (Okoli and Kodet, 2015), socio-economic status (Moor et al., 2015) and positive attitude towards tobacco (Bidstrup et al., 2009). There are also school factors, such as school policies that allow smoking (Barnett et al., 2007; Kuipers et al., 2016; Yanez et al., 2013), school climate (Lemma et al., 2015; Yanez et al., 2006) and that could influence smoking onset. Moreover, tobacco related policies, such as policies to restrict exposure of youth access to tobacco and tobacco excise tax could influence the smoking prevalence (Forster et al., 2007).

The theory of triadic influence integrates variables and processes from many sociological and psychological theories to describe proximal and distal influences on smoking behavior (Flay, 1999). Distal influences are broad and relatively stable, and they are causes that individuals have little control and can arise from the person (intrapersonal: genetic and personality factors), the situation (interpersonal: family, socioeconomic status, school) or the broader environment (access policies, mass media, socio-cultural environment) and their interaction. Proximal causes are more immediate precursors to a specific behavior and are under the control of an individual, although still influenced by the distal and ultimate factors. These proximal influences are cognitive and affective in nature: attitudes towards the behavior, social normative beliefs, self-efficacy, and intentions.

Although smoking prevention in the school setting is one of the most feasible and appropriate strategies to reduce tobacco consumption the effectiveness of smoking prevention programs in schools is unclear. The Hutchinson Smoking Prevention Project (Peterson Jr. et al., 2000), despite a rigorous designed and implemented study evaluated a 4-year intensive intervention and did not show positive results.

Moreover, a systematic review of smoking prevention programs in schools only had limited success (Thomas et al., 2013), and some of the programs believed to be effective had methodological flaws, conflicts of interest and inconsistent positive results (Gorman, 2003).

In this article, we report the results of a smoking prevention education program, a multifactorial program based on the theory of triadic influence (ITACA) (Flay, 1999). This program consists of a school curriculum that employs a comprehensive social influence approach, and an intervention orientated towards families, teachers, and schools.

2. Materials and methods

2.1. Design and study population

The effectiveness of the smoking prevention program was evaluated using a cluster-randomized controlled trial, with stratification by school-level tobacco consumption at baseline. The clusters were the different municipalities in the Balearic Islands, and the randomization was stratified based on a school survey about the prevalence of tobacco use in the 4th grade (15–16 year-olds). We defined three strata based on the results of this survey: 1) Low (0–9%), 2) Medium (10–19%) and 3) High (> 19%). In municipalities containing more than one secondary school, the secondary school to be included was determined through a randomization process. If the selected school declined to participate, another school from the same municipality was invited. We selected a municipality-level clustered randomized design, rather than randomization of classes or schools, to avoid contamination in the control group.

The populations of the included municipalities varied from 11,000 to 30,000. A total of 26 eligible schools were invited to participate, and 22 accepted and were randomized to one of the study arms. Schools allocated to the control arm received no smoking-prevention activities. A detailed research protocol was published elsewhere (Leiva et al., 2014).

The source population was students attending the first course of compulsory secondary education (12 to 13 years-old) in two consecutive academic periods. Written informed consent was obtained from all students and at least one parent per student, according to the

declaration of Helsinki.

2.2. Intervention

The ITACA smoking prevention education program is a 4-year smoking prevention program, originally designed for students in secondary education who are 12 to 16 years-old. The program was implemented between 2010 and 2014. ITACA is a cognitive-behavioral intervention that is based on the social-influences model, and is integrated into schools' regular curricular activities. The main components of this intervention and the activities to be performed are detailed elsewhere (Leiva et al., 2014). Each school designated a coordinator to carry out the intervention and established a communication system for the coordinator, teachers, and project researchers to report effectiveness of implementation.

The 4-year curricular component consisted of 22 lessons that were each approximately 50 min long: 8 lessons were integrated into the environmental sciences curriculum, 6 into the social sciences curriculum, 2 into the physical education curriculum, 1 into the mathematics curriculum, and 5 as student tutorials.

The components of the social-influences model include teaching students to identify the social influences that encourage initiation of smoking (e.g. tobacco company advertising campaigns, peer pressure), providing information about the harmful effects of smoking, and nurturing skills that lead to rejection of smoking. The curriculum included anti-advertising workshops designed to sensitize participants to the power of tobacco advertising campaigns. The intervention also sought to debunk false beliefs about tobacco; encourage the use of healthy methods for coping with emotions, stress, and peer pressure; and help students develop interpersonal relationship skills, self-esteem, strategies for accepting rules and limits, critical thinking skills, problem-solving skills, and the ability to recognize risky situations. The classroom sessions were provided by teachers trained in the different components of the intervention, smoking prevention, and health. There were 7 lessons in the first year (ages 12–13), 6 lessons in the second year (ages 13–14), 5 lessons in the third year (ages 14–15), and 4 lessons in the fourth year (ages 15–16). All lessons were age-appropriate and relevant to the students' curricula. All the teachers involved in the intervention reported to the school coordinator the total number of session classroom lessons.

2.2.1. Families

The parents of all participants met with teachers at least once per year, at the beginning of each academic term, and received information about the intervention. These meetings focused on encouraging parents to have an appropriate attitude towards use of recreational drugs; recognize situations that create a risk for adolescents; establish rules and limits; be sensitive to the role that family plays in tobacco use; and participate in the smoke-free home initiative. At least once per year, a workshop on smoking cessation was offered to the participating families of each municipality.

Parents also received leaflets about smoking in adolescents. These leaflets contained answers to questions frequently asked by families, and support material from the curricular sessions, so that parents and students can work together. Parents also received information on making the home a smoke-free place. Finally, parents had access to a webpage that offered information on the school intervention, tips on how families can help prevent children from smoking, and advice on smoking cessation in adolescents.

2.2.2. Teachers and schools

Teachers who delivered the interventions were trained in smoking prevention by a 20 h on-line course. The local government boards of education officially recognized this training course.

Classroom lessons were in accordance with each school's internal rules, and teachers were instructed on skills related to smoking

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