Research paper

Effectiveness evaluation of the school-based drug prevention program *#Tamojunto* in Brazil: 21-month follow-up of a randomized controlled trial

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ABSTRACT

Introduction: A school-based randomized controlled trial was conducted in 2014/2015 with students in 7th and 8th grades in 72 public schools in 6 Brazilian cities. A total of 5028 students were linked (75, 7%) in at least one of the two waves of follow-up (9 months and 21 months later). The principal research question was whether this 12-lesson program delays the initiation of alcohol, tobacco, inhalants and binge drinking among early adolescents when compared to usual care, that is, no prevention program in Brazilian schools, after 21 months of follow up.

Methods: Cox regression models were adjusted to evaluate the incidence of drug use. Generalized linear latent mixed models (GLLAMM) were used to evaluate changes in the prevalence of each drug over time and between groups.

Findings The incidence analysis showed a negative effect of the program for alcohol initiation (aHR = 1.13, 95%CI 1.01; 127) but an opposite protective effect for the initiation of inhalant use (aHR = 0.79, 95%CI 0.66; 0.95). After 21 months, the prevalence of past-year use of alcohol changed from 30.1% to 49.8% in the intervention group and from 29.9% to 45.8% in the control group. Adolescents in the intervention group were 30% more likely to have reported past-year use of alcohol than students in the control group at 21 months (aOR = 1.30, 95%CI 1.02; 1.65). No effects of the program on past-month drug use were found. The Brazilian version of the *Unplugged* program may be misinterpreted by public school students, perhaps arousing their curiosity regarding alcohol use.

Introduction

The results of a national epidemiological survey revealed a high prevalence of alcohol (42.4%), tobacco (9.6%) and illicit substance (25.5%) consumption among Brazilian adolescents, which is associated with early initiation (i.e., between 12 and 14 years of age) (Carlini et al., 2010; Malta et al., 2011). However, it is well known that initiation of drug use at an early age puts young people at serious risk of developing future problems, such as poorer cognitive functioning, addiction and increased vulnerability to developing psychiatric disorders (Camchong, Lim, & Kumra, 2017; Flórez-Salamanca et al., 2013; James, James, & Thwaites, 2013; Squeglia & Gray, 2016).

These findings point to the need for the implementation of interventions designed to prevent drug use in this population. To address this issue, the Brazilian Ministry of Health (BMH), together with the UNODC Brazil (United Nations Office on Drugs and Crime in Brazil), conducted a transcultural adaptation and implementation of *Unplugged*, a European school-based drug prevention program (Kreeft et al., 2009). *Unplugged* is a Comprehensive Social Influence program based in the integration of multiple theories such as Social Learning, Problem Behavior, Reasoned Action-Attitude, and Social Norms. The theories are integrated and intertwined, creating a complex model that offers a Social Competence and Social Influence curriculum, extensively described by Vadrucci et al. (2016). The model assumes that drug use initiation results from social influences, through which adolescents develop erroneous perceptions of the frequency and acceptability of drug consumption (Giannotta et al., 2014). Through interactive techniques, the *Unplugged* curriculum supports the development of life skills such as communication, assertiveness, critical thinking, coping strategies, goal setting, decision making, and problem-solving; skills to resist

the pressure to use drugs; and the reinforcement of self-commitment to remain a non-user (Kreeft et al., 2009). The program is intended to enhance protective factors for drug use, by strengthening personal and interpersonal skills of adolescents that are thought to reduce the effects of social influence by modifying attitudes, beliefs, and normative perceptions (Giannotta et al., 2014; Sussman et al., 2004). The details of each component and the complete theoretical model of the *Unplugged* program was published elsewhere (Vadrucci et al., 2016).

In 2013, a national prevention system was implemented by the Brazilian Ministry of Health (BMH), disseminated through the structure of local State and Municipal Secretariats of Health and Education in at least 10 Brazilian states (Brasil, 2017). The system was created in response to the "National Integrated Plan to Combat Crack and Other Drugs", which focused on reducing drug use demands of the population by implementing prevention programs in schools and communities. This prioritized drug prevention in social and public health policy agendas (Decree 7.637, December 8, 2011). Accordingly, the BMH, together with the UNODC Brazil (United Nations Office on Drugs and Crime in Brazil), conducted transcultural adaptation and implementation of three evidence-based prevention programs that had positive results in other countries: *Unplugged* (called *#Tamojunto* in Brazil) for 7th- and 8th-graders in middle schools; the Good Behavior Game (called Elos in Brazil) for children in elementary schools (Schneider et al., 2016) and the Strengthening Families Program (called Famílias Fortes in Brazil), which focused on families in the public welfare system (Miranda & Murta, 2016).

In a broad multicenter study in seven European countries (Faggiano et al., 2008), Unplugged showed significant reductions in the number of episodes of drunkenness and frequent marijuana use in the past 30 days (Faggiano et al., 2010). Positive effects of the program were also found in an independent study conducted in the Czech Republic, which showed reductions in the consumption of tobacco (any, daily and heavy smoking), marijuana (any and frequent use) and any other drug (Gabrhelik, Duncan, Lee, et al., 2012).

In Brazil, a non-randomized controlled trial was conducted in 2013 to test the efficacy of the first Brazilian version of *Unplugged* for drug use prevention among 2185 adolescents in 62 classes in public schools in three Brazilian cities. The objective of this study was to evaluate the preliminary results and the feasibility of its adaptation to the Brazilian culture, with high control of fidelity in the implementation process, as expected in an efficacy trial. The control group showed increased use of marijuana, alcohol and inhalants in the past year as well as increased binge drinking (i.e., the consumption of 5 or more drinks of alcohol) in the previous month compared to the intervention group. These findings suggest that the program has the potential to decelerate the expected increase in drug use during adolescence (Sanchez et al., 2016). Although positive results were found in European schools and, in smaller amounts, in the efficacy study conducted in Brazil in 2013, it is important to evaluate the effectiveness of this program in the Brazilian context with a randomized controlled trial and real-world conditions (Barrera & Castro, 2006), especially since the results may not be the same in large-scale dissemination as public policy and in a more robust study design. The failure to conduct evaluations of the effectiveness of the intervention in different cultures may promote ineffective or even harmful programs (Moos, 2005).

Among the 3 programs, only *Unplugged* was submitted to an effectiveness study that was performed between 2014 and 2105 through a randomized controlled (RCT) trial in 6 cities that were part of the national prevention system. The short-term results of this RCT were published (Sanchez et al., 2017) and showed a negative effect for alcohol initiation at the 9-month follow-up, concomitant to a protective effect on the delay of first use of inhalants. Twenty-one months after the baseline collection, a new follow-up was performed to address the maintenance of this effect over a longer time interval, which was a key issue for the stakeholders from BMH.

Therefore, the present study aims to evaluate the effectiveness of the school program *#Tamojunto*. The principal research question is whether this program delays the initiation of alcohol, tobacco, inhalants and binge drinking among early adolescents when compared to usual care, that is, no prevention program in Brazilian schools, after 21 months of follow up.

Methods

Study design

A two-arm school-based RCT was conducted with students in 7th and 8th grades in 72 public schools in 6 Brazilian cities (São Paulo, Federal District, São Bernardo do Campo, Florianópolis, Fortaleza and Tubarão) located in 4 Brazilian states. The study compared the integration of the prevention program *#Tamojunto* into school curricula (intervention condition) with usual curricula in Brazil (i.e., no prevention program; control condition).

Schools randomly selected to take part in the intervention group received 12 lessons of the *#Tamojunto* program from March to June 2014, whereas the control schools had "treatment as usual". The schools participating in the study attested that no other prevention programs would be simultaneously implemented.

Seventy-two schools were randomly selected proportional to the municipality (stratum) number of schools. A second allocation determined whether each school would be assigned to the control or intervention group according to a random list, maintaining a 1:1 allocation ratio per municipality. The randomization was performed by a data scientist hired to perform this work (not part of the implementation or evaluation team).

The baseline assessment of substance use was conducted during the second week of February 2014, and the first follow-up assessment was conducted 9 months later during the third and last weeks of November 2014. The last follow-up was conducted 21 months after the baseline in November 2015. The school year in Brazil goes from February to December. Data were collected simultaneously in the control and experimental schools at the three stages of evaluation: baseline, 9-month follow-up, and 21-month follow-up. The trial was registered at the Ministry of Health Brazilian Register of Clinical Trials - REBEC, number RBR-4mnv5g and the protocol publicly available at this registry (http://www.ensaiosclinicos.gov.br/rg/?q=tamojunto). The implementation and cultural adaptation were the responsibility of the BMH, and the evaluation was performed by an independent team from 2 universities. This study was approved by the Ethics in Research Committee at Universidade Federal de São Paulo (#473.498) and Universidade Federal de Santa Catarina (#711.377).

Sample size and population

The target population was students in the 7th and 8th grades in the geographical areas of the participating cities. In these grades, the expected mean age is 12 to 13 years old. The school drawing occurred in each participating municipality using the complete list of all public middle schools in the locations as a database for randomization according to the national registration list of schools from the INEP (Instituto Nacional de Estudos e Pesquisas Educacionais Anísio Teixeira). Randomization was performed using the *rand* command in Excel.

Based on the sample size calculation (Lwanga & Lemeshow, 1991) for a given power of 80%, a significance level of 5% and a difference between groups in binge drinking of 1.5 percentage points (i.e., from 5% to 3.5%), the necessary sample size for each study arm was calculated to be 2835. Taking into account a possible loss of 50% of subjects, a sample of 4253 adolescents in the intervention group and 4253 adolescents in the control group were defined, totaling 8506 adolescents. Details on sampling were described in a previous study (Sanchez et al., 2017).