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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A B S T R A C T

*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

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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).

In each of the intervention schools, all 8th-grade classes were invited to participate in the *#Tamojunto* program, and the school selected a teacher from each class to receive a 16-hour training on program delivery. In Fortaleza, Santa Catarina and Tubarão, the 7th-grade classes of the selected schools were also included because these cities were in the process of changing the age of students assigned to each grade and because the State Education Secretariat requested the inclusion of the 7th-grade classes in the study.

### Intervention

The *Unplugged* program was designed by the EU-DAP group (Kreeft et al., 2009) and consists of 12 weekly classes (4 one-hour classes on attitudes and knowledge about drugs, 4 classes on social and interpersonal skills, and 4 classes on personal skills) with an average duration of 50 min, taught to students by trained teachers and guided by the student and teacher manuals. Both manuals are open access and are available in several languages on the website www.eudap.net. The transcultural adaptation of the program to Brazil was performed by the BMH team (details are described in Sanchez et al., 2017).

The teachers who delivered the program attended a 16-hour training facilitated by coaches trained by the European developers, the master trainers of the EU-DAP Intervention Planning Group (Gabrhelik, Duncan, Lee, et al., 2012). At the end of each class, teachers had to complete a fidelity questionnaire to assess the dose of the program delivered. To guarantee fidelity, teachers were supervised monthly by the coaches from the BMH who had facilitated the initial training.

### Instrument and variables

The instrument used for data collection was based on 3 other questionnaires: 1) the EU-Dap questionnaire used in previous studies of the effectiveness of *Unplugged* (Faggiano et al., 2008), adapted to Portuguese (Cainelli de Oliveira Prado et al., 2016); 2) the questionnaire of the World Health Organization for drug use among students (Carlini et al., 2010); and 3) the PeNSE questionnaire (Pesquisa Nacional de Saúde do Escolar), used by the Brazilian Ministry of Health to regularly evaluate middle-school students' health risk behaviors, such as violence (Penna, 2010).

The questionnaire evaluates a set of variables, such as sociodemographic data and past-month and past-year use of the following drugs: alcohol, tobacco, marijuana, inhalants, cocaine and crack. It also evaluates the practice of binge drinking (the consumption of five or more alcoholic drinks on a single occasion) in the past month and past year. The evaluation of socio-economic status (SES) was assessed using the ABEP score (Socioeconomic scale from Associação Brasileira de Empresas de Pesquisa) (Brazilian Market Research Association, 2015).

In addition, to evaluate the incidence of drug use according to the first-time use of each drug, we used the number of students who reported never having used the drug at the baseline survey (denominator) and the number of these students who reported lifetime use at follow-up (numerator).

The outcomes analyzed were the incidence of first drug use, the prevalence of use in the past 30 days (use in the past month = yes vs. no) and in the past 12 months (use in the year = yes vs. no) of the following drugs: alcohol, tobacco, marijuana, inhalants and a binge drinking pattern of alcohol consumption. The adjustment variables were school, class, city, gender, SES and age. Cocaine and crack were not included due to very low prevalence at the three time points.

To pair (link) the questionnaires of each subject at the three time points of study (baseline and follow-up), students provided a secret code involving letters and numbers, as previously described (Sanchez et al., 2017). The secret codes were linked using the Levenshtein algorithm, which identifies similarities among a set of characters (Levenshtein, 1965).

### Analysis

Participants were analyzed in the group to which they were randomized, and all students who had at least one follow-up beyond the baseline were included in the analysis. The parameters of interest were the relative differences between groups in changes in the odds of past-month drug use (i.e., alcohol/binge drinking, tobacco, marijuana, inhalants) over time and relative differences in the incidence of drug use (i.e., first use alcohol/binge drinking, tobacco, marijuana, inhalants) between groups. Descriptive statistics were obtained for the variables "past-month use" (prevalence) and "first use" (incidence) of alcohol/binge drinking, tobacco, inhalants and marijuana.

To account for the hierarchical structure of the data and the school cluster effect, multilevel modeling approaches were used in the analysis (Murray, Varnell, & Blitstein, 2004). Three-level random effect models (level 1: repeated time (baseline and 21 months) observations nested within students; level 2: students clustered within school; level 3: school) were used to evaluate the change in odds ratios of past-month substance use over time. The explanatory variables used were group, time of assessment, and their interaction, controlling for sex, age, municipality and SES. The interaction term, called the *#Tamojunto* effect, tested the equality of the changes in odds from baseline to follow-up between the intervention groups. These results were presented as the odds ratio (OR) and 95% confidence interval (95% CI). These models were fitted with Stata program Generalized Linear Latent Mixed Models (GLLAMM) (Rabe-Hesketh, Skrondal, & Pickles, 2004).

To evaluate the incidence of drug use according to any first-time use reported (9 or 21 months), we analyzed the number of students who reported that they had never used the drug at baseline (denominator) and the number of these students who reported lifetime use at follow-ups (numerator). For the incidence of first use, Cox regression models were adjusted for the same potential confounders used in the prevalence models using cluster (school) robust standard errors. The results of first use were presented as "hazard ratios" (HR) with their respective 95% CIs. These analyses considered both the 9-month follow-up and the final 21-month follow-up assessments.

All analyses were performed using STATA/SE 13.1, and p-values under 0.05 were considered significant.

### Results

A total of 6658 students in 261 classes from the 72 schools investigated answered the baseline questionnaire, 5957 students answered the follow-up questionnaire at 9 months (63, 3% linked) after baseline, and 4434 students answered the follow-up questionnaire at 21 months (54, 6% linked) after baseline (Fig. 1). The database analysis consisted of 5007 adolescents (757% linked) with no missing data on gender or age who might have had their data linked between at least two time points of the study, with one of those time points necessarily being the baseline. Of those 2472 students (74, 0% linked) from intervention group and 2556 students from control group (77, 0% linked).

Table 1 shows that both intervention and control groups were homogenous with respect to sex, age and socioeconomic classification by the ABEP scale at baseline.

Table 2 shows the primary research question: the incidence of use among those who reported that they had never used the respective drug at the baseline and then reported first use during the study. The data show that the incidence of first use of alcohol was reported by 52.1% of the adolescents in the intervention group and by 47.7% in the control group. In the 21 months of follow-up, the intervention group had a 13% higher risk (95% CI: 1.01; 1.27) of initiating their first use of alcohol than the control group. However, for inhalants, the effect was the opposite; there was a greater risk of engaging in first use of inhalants in the control group than in the intervention group, with a 21% lower risk of use in the intervention group (HR = 0.79; 95% CI: 0.66; 0.95).
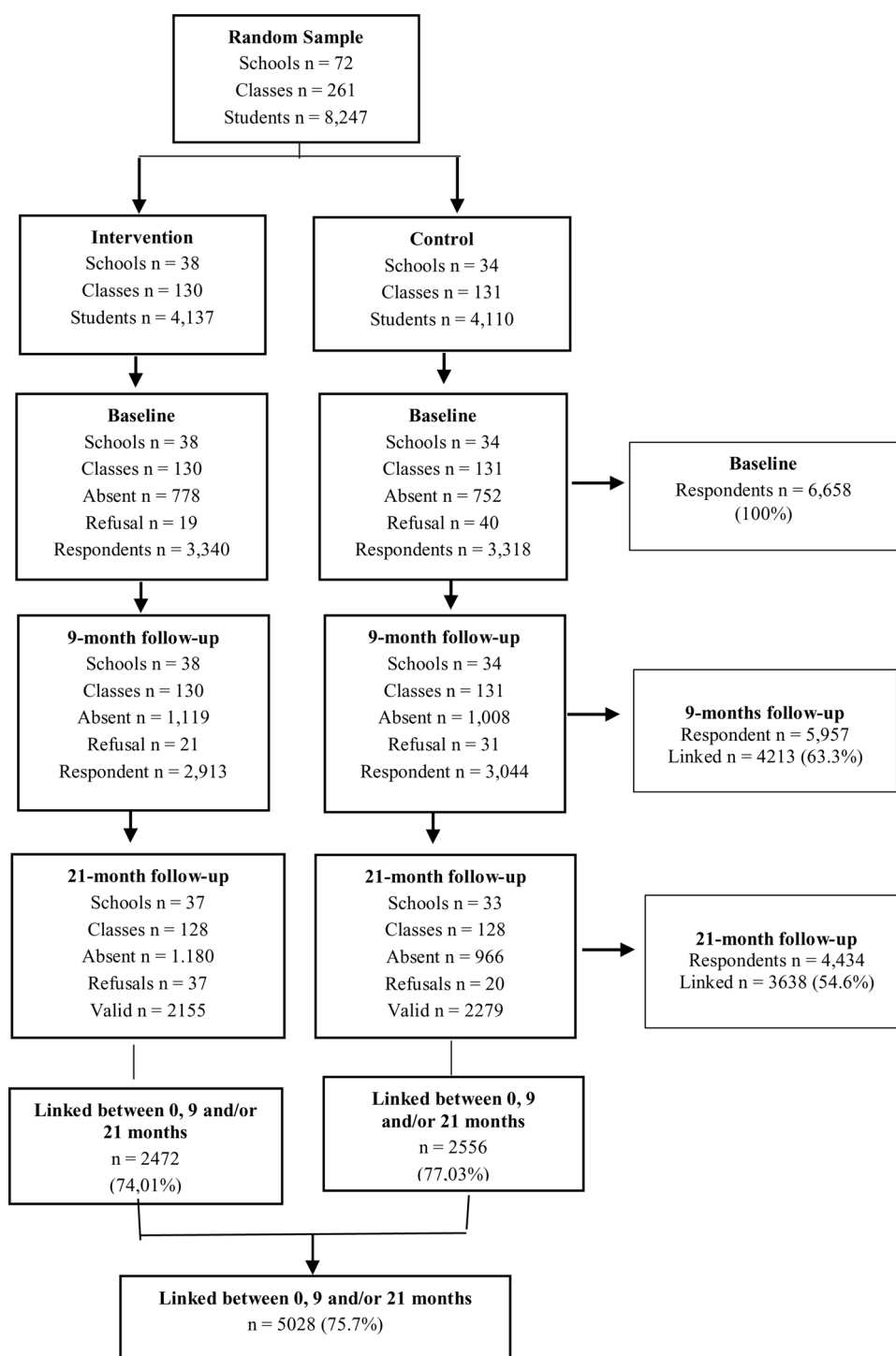
**Fig. 1.** Flowchart of controlled randomized trial #*Tamojunto (Unplugged)*, 2014/2015.

Considering the prevalence of drug use at baseline, it was observed that the prevalence of past-year drug consumption was similar between the intervention and control groups, showing no statistically significant differences between groups (see Table 3; p-values for the between-group comparisons are not presented in the tables). No program effect was found for binge drinking, tobacco, marijuana and inhalants (Table 3). However, it is important to note that although the association was not significant, there was a tendency in the odds values favoring the experimental group since they presented values lower than 1.

Despite the growing use of alcohol in both groups, the intervention group showed a higher increase of alcohol use (prevalence of past-year

use begins at 30.1% and ends at 49.8%) compared to the control group (prevalence of past-year use begins at 29.9% and ends at 45.8%). This finding indicates that the intervention group had a 30% higher chance of using alcohol in the past year than the control group (OR = 1.30; 95% CI: 1.02; 1.65).

Comparisons between the groups regarding past-month use of to-bacco (Table 4) found no program effect on the principal research questions (p > 0.05). Although the program has an effect after 21 months on reported use of alcohol in the past year, this effect is lost when evaluating more recent alcohol consumption (past month).

As this study was a school trial, students recruited from within the

**Table 1**

Distribution of 5007 adolescents with data matched according to socio-demographic variables and allocation group in the randomized controlled trial of the #Tamojunto program, according to baseline. Brazil.2014–2015.

| | Total (N = 5007) | | Group | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| | | | Intervention Arm (N = 2460) | | Control Arm (N = 2547) | | |
| | N | % | N | % | N | % | |
| **City** | | | | | | | |
| Distrito Federal | 445 | 8,9 | 232 | 52,1 | 213 | 47,9 | |
| Fortaleza | 354 | 7,1 | 145 | 41,0 | 209 | 59,0 | |
| Tubarão | 261 | 5,2 | 124 | 47,5 | 137 | 52,5 | |
| Florianópolis | 694 | 13,9 | 295 | 42,5 | 399 | 57,5 | |
| São Bernardo do Campo | 718 | 14,3 | 368 | 51,2 | 350 | 48,6 | |
| São Paulo | 2535 | 50,6 | 1304 | 51,1 | 1244 | 48,8 | |
| **Gender** | | | | | | | |
| Boys | 2459 | 49,1 | 1229 | 50,0 | 1230 | 48,3 | |
| Girls | 2548 | 50,9 | 1231 | 50,0 | 1317 | 51,7 | |
| **Age Distribution** | | | | | | | |
| 11 years | 110 | 2,2 | 51 | 2,0 | 59 | 2,3 | |
| 12 years | 2702 | 54,0 | 1288 | 52,4 | 1414 | 55,5 | |
| 13 years | 1692 | 33,8 | 860 | 35,0 | 832 | 32,7 | |
| 14 years | 405 | 8,1 | 207 | 8,4 | 198 | 7,8 | |
| 15 years | 98 | 1,9 | 54 | 2,2 | 44 | 1,7 | |
| **School Grade** | | | | | | | |
| 7th | 715 | 14,3 | 301 | 12,2 | 414 | 16,2 | |
| 8th | 4292 | 85,7 | 2159 | 87,8 | 2133 | 83,8 | |
| **SES**[c] | | | | | | | |
| A | 205 | 4,1 | 100 | 4,1 | 105 | 4,1 | |
| B1 | 401 | 8,0 | 207 | 8,4 | 194 | 7,6 | |
| B2 | 1651 | 33,0 | 814 | 33,1 | 837 | 32,9 | |
| C1 | 1625 | 32,5 | 812 | 33,0 | 813 | 31,9 | |
| C2 | 908 | 18,1 | 439 | 17,8 | 469 | 18,4 | |
| DE | 217 | 4,3 | 88 | 3,6 | 129 | 5,1 | |

a. Chi-Square Test.
b. Student's T-Test.
c. Socioeconomic classification according to ABEP.

same school could have shown similarities; this similarity was expressed using the intraclass correlation coefficient (ICC, Table S1, in Supplementary file). For past year use, the lowest observed school ICC was for *binge drinking* (ICC = 0.012, 95%CI 0.005-0.029), and the highest school ICC was for marijuana use (ICC = 0.035, 95%CI 0.014-0.087). Regarding past month use of substances, the school ICC varied from 0.010 (95%CI 0.003-0.031) for binge drinking to 0.027 (95%CI 0.007-0.097) for marijuana.

Regarding the results related to the fidelity of the implemented intervention, a total of 87% of the schools completed the 12 program lessons. The other 13% ended the program between lessons 4 and 11 for two main reasons: the teachers went on medical leave or were not comfortable implementing the program. 72% of classes taught were

given in full, with the execution of all activities provided in the protocol.

### Attrition

The students who could be linked across at least one time point of follow-up consisted of a modestly but significantly higher proportion of girls, with a lower average age as well as more students in the 8th grade when compared to cases that could not be linked. Considering the differences in retention between the groups, there were also more losses in the intervention group than in the control group. Notwithstanding this result, there was more drug use reported by students who were found only at the baseline and were not followed up at other time points than by students who participated in at least one of the follow-up assessments. Except for the use of inhalants (use in the past month and past year), there were no statistically significant differences between the groups in the baseline prevalence of drug consumption (Table S2, in Supplementary file).

### Discussion

This study evaluated the effectiveness of a universal program to prevent drug misuse implemented in Brazilian schools as part of a public policy that aimed to test whether the program delays the initiation of use of alcohol, tobacco, inhalants and binge drinking among early adolescents when compared to usual care, that is, no prevention program in Brazilian schools. The results showed an increase in drug use over 21 months in the two groups (intervention and control) for all drugs evaluated. However, the findings revealed significant differences between the groups in patterns of use for alcohol and inhalants when "first use" and "use in past year" were considered as outcome measures. The Society for Prevention Research highlights the importance of this type of study to assess the evidence of the effectiveness of a prevention program before it is disseminated to the general population (Flay et al., 2005).

This analysis suggests that the program has a persistent negative effect for first use. We have previously (Sanchez et al., 2017) identified this effect in a short-term analysis (9 months only). However, it was maintained 12 months later, which indicates a possible larger undesirable effect since even after 21 months, we found a higher incidence of alcohol initiation in the intervention group. This finding warrants considerable concern given that an adequate prevention measure should focus on delaying the onset of alcohol consumption into late adolescence (Hingson, Heeren, & Winter, 2006; Pitkänen, Lyyra, & Pulkkinen, 2005) since the early onset of alcohol use increases the chances of abuse and dependence in adulthood (Buchmann et al., 2009; McCarty et al., 2004) and *binge drinking* in late adolescence (Sanchez et al., 2013).

Our first hypothesis to explain these negative effects is non-ideal adherence to the curriculum. In a study that evaluated the program's

**Table 2**

Distribution of adolescents exposed to the **FIRST USE** of alcohol and other drugs over the 21-month follow-up according to group. Results of multivariate analysis of the randomized controlled trial #Tamojunto.

| Intention to Treat (ITT) | GROUPS | | | | | | Cox Multivariate* | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | INTERVENTION | | | CONTROL | | | | | |
| | Never Used at Baseline | Used at 21 months | % | Never Used at Baseline | Used at 21 months | % | HR* | (95% CI) | p[a] |
| Alcohol | 1309 | 682 | 52.1 | 1376 | 656 | 47.7 | 1.13 | 1.01 - 1.27 | 0.040 |
| *Binge drinking* | 2043 | 496 | 24.3 | 2156 | 525 | 24.3 | 0.99 | 0.85 - 1.16 | 0.929 |
| Tobacco | 2290 | 293 | 12.8 | 2376 | 307 | 12.9 | 0.99 | 0.78 - 1.26 | 0.959 |
| Inhalants | 2018 | 319 | 15.8 | 2098 | 412 | 19.6 | 0.79 | 0.66 - 0.95 | 0.013 |
| Marijuana | 2371 | 223 | 9.4 | 2473 | 262 | 10.6 | 0.89 | 0.69 - 1.13 | 0.343 |

*Adjusted by sex, age, city and SES. **Using cluster (school) robust standard errors.**

**Table 3**

Comparison between groups and evaluation of the #Tamojunto effect on **PAST-YEAR USE** of alcohol and other drugs among students participating in the randomized controlled trial of the #Tamojunto program.

| | INTERVENTION | | | | | CONTROL | | | | | #Tamojunto Effect[b] | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Baseline | | 21-month Follow-Up | | | Baseline | | 21-month Follow-Up | | | 21-month Follow-Up | |
| Past year use | N | % | N | % | OR[a] (95% CI) | N | % | N | % | OR[a] (95% CI) | OR[b] (95%CI 95%) | p |
| Alcohol | 732/2432 | 30.1 | 882/1771 | 49.8 | 4.05 (3.18 – 5.15) | 755/2526 | 29.9 | 849/1854 | 45.8 | 3.12 (2.52 – 3.87) | 1.30 (1.02 – 1.65) | 0.032 |
| *Binge drinking* | 346/2418 | 14.3 | 448/1760 | 25.4 | 3.12 (2.41 – 4.04) | 344/2519 | 13.7 | 460/1844 | 24.9 | 3.14 (2.46 – 4.03) | 0.99 (0.75 – 1.31) | 0.954 |
| Tobacco | 75/2425 | 3.1 | 130/1759 | 7.4 | 3.37 (2.36 – 4.81) | 66/2519 | 2.6 | 122/1846 | 6.6 | 3.52 (2.43 – 5.09) | 0.96 (0.59 – 1.55) | 0.858 |
| Inhalants | 208/2423 | 8.6 | 175/1764 | 9.9 | 1.21 (0.95 – 1.54) | 196/2520 | 7.8 | 202/1845 | 10.9 | 1.60 (1.26 – 2.02) | 0.86 (0.66 – 1.13) | 0.283 |
| Marijuana | 47/2421 | 1.9 | 143/1754 | 8.1 | 7.52 (3.87 – 14.61) | 34/2522 | 1.3 | 133/1846 | 7.2 | 9.73 (4.75 – 19.90) | 0.77 (0.43 – 1.40) | 0.395 |

a. Comparison between groups obtained via GLLAMM model, adjusted for sex, age, city and SES.
b. Effect of interaction between group and time named #Tamojunto effect obtained via GLLAMM model, adjusted for sex, age, city and SES.

fidelity through semi-structured interviews with the teachers who taught the program, there was an adaptation in the classroom to enable timely implementation of the program, suggesting that the lessons that had been outlined in the teachers' manual were not always effectively or appropriately executed (Brasil, 2017). Failures in these aspects may have compromised the expected results even after the teachers' training and supervision of the implementation. Failures in guaranteeing implementation fidelity and the dose projected can compromise the expected results of a program (Dusenbury et al., 2003). However, because this was an effectiveness study and the implementation was measured as part of public policy, the study estimated the large-scale effect and lacked quality control of the lessons taught in the classroom.

Another possible explanation is the cultural adaptation of the program. We must consider that there may have been a misinterpretation of the lessons' content concerning alcohol-related information and social norms because the negative effect was not found for other drugs, perhaps because the normative beliefs assumed by the program cannot be easily transferred from the European to the Brazilian context. The ease of access and excess consumption of alcohol already present among adolescents may have interfered with the effectiveness of program activities in changing beliefs about alcohol (De La Rosa, 2002; Strøm, Adolfsen, Fossum, Kaiser, & Martinussen, 2014).

In a country such as Brazil, which has a deeply ingrained culture of alcohol consumption and a weak regulatory framework controlling the sale and promotion of alcohol (Laranjeira, 2007), an ideal public health response to adolescent alcohol misuse would be a combination of a school-based curriculum, such as #Tamojunto, and programs aimed at the family and community, with an emphasis on gradual change in beliefs and practices rooted in society (Caria, Faggiano, Bellocco, & Galanti, 2011).

It is important to raise concerns about the adaptation made in Lesson 3 of the Brazilian version of the students' manual. The lesson "Choices - Alcohol, Risk and Protection" contains sentences from the original version of *Unplugged* that were excluded in the *#Tamojunto* version, such as, "Do not drink alcohol because it is not healthy (….) particularly at your age", and reflexive questions were added, such as, "Why do some people drink alcohol but not get drunk?" These changes can be associated with a more permissive discourse on alcohol use among adolescents and do not clarify the message of non-use of alcohol in adolescence. At this stage, validation of the core components of the Brazilian version of the program would need to be performed by the developers to guarantee the maintenance of the logic model of the intervention.

Although European data suggest important effects of the program on recent marijuana use and drunkenness (2010, Faggiano et al., 2008), our study does not point in this direction. However, is important to mention that although the Brazilian version of the program favors the early initiation of alcohol, it concomitantly reduces the chance of inhalant initiation, an outcome that, when delayed, may reduce a number of behavioral and health problems in adulthood (Ober, Miles, Ewing, Tucker, & D'Amico, 2013). However, it is necessary to hypothesize that there may have been a substitution in experimenting with drugs; that is, despite the unexpected effect of the program on the stimulation of alcohol use, it may have had a substitutive effect on inhalant use.

Finally, it should be emphasized that this study has limitations. The major limitation of this trial is the differences in follow up data due to the losses over the time. We found an excessive number of absent students in the classroom during the baseline data collection, as previously

**Table 4**

Comparison between groups and evaluation of the #Tamojunto effect on distribution of **PAST-MONTH USE** of alcohol and other drugs among students participating in the randomized controlled trial of the #Tamojunto program.

| | INTERVENTION | | | | | CONTROL | | | | | #Tamojunto Effect[b] | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Baseline | | 21-month Follow-Up | | | Baseline | | 21-month Follow-Up | | | 21-month Follow-Up | |
| Past month use | N | % | N | % | OR[a] (95% CI) | N | % | N | % | OR[a] (95% CI) | OR[b] (95% CI) | p |
| Alcohol | 351/2443 | 14.4 | 449/1771 | 28.2 | 3.47 (2.84 – 4.25) | 335/2537 | 13.2 | 492/1859 | 26.5 | 3.43 (2.81 – 4.18) | 1.01 (0.78 – 1.32) | 0.922 |
| *Binge drinking* | 276/2423 | 11.4 | 349/1762 | 19.8 | 2.56 (2.07 – 3.17) | 247/2517 | 9.8 | 327/1850 | 17.7 | 2.58 (2.08 – 3.20) | 0.99 (0.74 – 1.33) | 0.957 |
| Tobacco | 31/2430 | 1.3 | 60/1767 | 3.4 | 4.10 (2.33 – 7.22) | 29/2530 | 1.1 | 59/1852 | 3.2 | 4.34 (2.42 – 7.74) | 0.94 (0.45 – 1.99) | 0.883 |
| Inhalants | 61/2429 | 2.5 | 64/1767 | 3.6 | 1.51 (1.03 – 2.22) | 66/2528 | 2.6 | 83/1856 | 4.5 | 1.88 (1.31 – 2.68) | 0.81 (0.48 – 1.35) | 0.416 |
| Marijuana | 24/2433 | 1.0 | 88/1764 | 5.0 | 8.20 (4.56 – 14.76) | 14/2526 | 0.5 | 71/1856 | 3.8 | 11.08 (5.47 – 22.41) | 0.74 (0.33 – 1.68) | 0.473 |

a. Comparison between groups obtained via GLLAMM model, adjusted for sex, age, city and SES.
b. Effect of interaction between group and time named #Tamojunto effect obtained via GLLAMM model, adjusted for sex, age, city and SES.

described in a national survey, which found that approximately 20% of students are regularly absent in public schools (Penna, 2010). Furthermore, there was attrition throughout the study. However, attrition is an expected limitation in RCTs, already found in other school-based prevention studies (Ariza et al., 2013; Newton, Teesson, Vogl, & Andrews, 2010; Shope, Dielman, Butchart, Campanelli, & Kloska, 1992). We identified differences in the prevalence of drug use among students who responded to at least one follow-up and those who responded only to the baseline questionnaire. One possible explanation for the losses occurring more frequently in the intervention group is the confirmation that the intervention was unsuccessful in preventing drug use among these students, once those who dropped out were significantly more likely to have higher drug use baseline prevalence, which is already expected in school-based prevention programs (Caria et al., 2011). We suggest that future studies explore the impact of the factors predicting drop out, which was not the scope of this study. Therefore, these results cannot be extrapolated to all students who were involved in the study. The clearly non-random loss to follow up pattern does not allow the use of regular imputation that depends on the presupposition of data missing at random or missing completely at random.

## Conclusion

This pioneering initiative in Brazil, conducted by the Ministry of Health to implement a preventive public policy and start a national evidence-based prevention system, is noteworthy. The results of this study suggest that the program components and their effects should be discussed before attempting broad, national expansion. Special attention should be given to the adaptation of Lesson 3 (about alcohol) and fidelity. An assessment of potential reasons that led to an effect contrary to the expected effect is crucial. It is necessary to focus on potential mediators of the effects, improve the training and supervision of teachers, and adjust the educational materials. At the same time, we encourage the adaptation and evaluation of other school-based drug-prevention programs with proven effectiveness in sociocultural environments similar to Brazil.

## Conflict of interest

The authors declare that they have no conflicts of interest.

## Ethics

All procedures in the present study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. This study was approved by the Ethics in Research Committees at the University of São Paulo (#473.498) and the Federal University of Santa Catarina (#711.377).

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