ORIGINAL PAPER

Effects of a School-Based Drug Prevention Program on Sexual Risk Behavior Among Adolescents in Brazilian Schools

Larissa F. Reis[1] · Juliana Y. Valente[1] · Zila M. Sanchez[1] · Pamela J. Surkan[2]

Abstract

Sexual risk behaviors are closely related to the use of alcohol, tobacco, and other illicit drugs as well as teen dating violence. School-based drug prevention programs that teach social and personal skills could potentially also reduce sexual risk behaviors. We examined the effects of the *#Tamojunto* program on youth sexual risk behaviors. A randomized controlled trial was conducted with 6391 7th and 8th grade students in 72 public schools in six Brazilian cities. Baseline data were collected prior to program implementation. Two waves of follow-up assessments occurred after 9 and 21 months. Analyses were performed taking into account the multilevel structure of the data. We used intention-to-treat to evaluate changes in the prevalence of sexual risk behaviors over time and between groups. Adolescent age ranged from 11 to 15 years, with a mean of 12.6 ± 0.8 years, and 51.0% were female. Among all participants, receipt of *#Tamojunto* was associated with higher risk of lifetime sex at 21 months follow-up (OR 1.27, 95% CI [1.03, 1.56]). Among girls, at 9 months follow-up, the program was associated with higher likelihood of having engaged in sex in the last month (OR 1.76, 95% CI [1.13, 2.74]). At 21 months follow-up, girls receiving the program were more likely to report engaging in condomless sex in the last month (OR 1.64, 95% CI [1.07, 2.50]). *#Tamojunto* may be ineffective and possibly harmful for preventing sexual risk behaviors, especially among girls. We suggest further investigation of the possible mediating role of life skills intervention components on girl's sexual behaviors.

Keywords Sexual risk behavior · School prevention · Adolescence · Drug use · Randomized controlled trial

Introduction

Adolescence is an important developmental stage in which youth may engage in sexual risk behaviors. Monitoring sexual behaviors during this vulnerable period is necessary to control sexually transmitted diseases (STDs) and unplanned pregnancies (World Health Organization, 2016). Also, early initiation of sexual intercourse is associated with condomless sex and with having multiple partners (Son et al., 2016).

According to national data from Brazil, 28.7% of ninth-grade students (mean age 14 years) reported lifetime sex. Among these sexually active adolescents, 24.7% didn't use condoms during the last sexual encounter (Oliveira-Campos et al., 2014).

Teen dating violence is a type of intimate partner violence (IPV) that includes several forms of aggression (e.g., physical, psychological, sexual or stalking). It is also associated with sexual risk behaviors, such as early initiation of sex, condomless sex and increased number of partners (Howard et al., 2007). Adolescent victims of dating violence report higher risk of depression, future IPV victimization (Exner-Cortens & Eckenrode, 2013; Foshee et al., 2013) and increased risk of alcohol and tobacco use (Lormand et al., 2013; Silverman et al., 2004). Substance use is a predictor of early initiation of sex before age 15 (Kugler et al., 2015) as well as condomless sex, HIV infection and dating violence (Borawski et al., 2015; MacArthur et al., 2012).

In fact, deviant behaviors are usually associated with each other, which means that participating in one deviant behavior

✉ Pamela J. Surkan
psurkan@jhu.edu

1 Department of Preventive Medicine, Universidade Federal de São Paulo, São Paulo, Brazil

2 Department of International Health, Johns Hopkins Bloomberg School of Public Health, 615 N Wolfe Street, Baltimore, MD 21205, USA

increases the possibility of engaging in another (Vadrucci et al., 2016). One reason could be related to sensation seeking, a personality characteristic reflecting an individual's tendency to pursue new and exciting stimuli that seems to be associated with most risk behaviors (Zuckerman et al., 1972). Brain development may also explain how adolescents behave. On one hand, the prefrontal cortex, the area of executive control function (e.g., self-control) requires a long time to develop, finally maturing in adulthood (Institute of Medicine [IOM], 2011). On the other hand, the limbic system, which develops more quickly compared to the prefrontal cortex, supports emotion and pleasure-seeking. The imbalance between these two regions during adolescence may lead to emotional as opposed to rational reactions (IOM, 2011). In these circumstances, risk-taking in adolescents may be accentuated (IOM, 2011). Notably, substance use and sexual risk behaviors tend to co-occur among adolescents, which amplifies the effects of both phenomena (U.S. Department of Health and Human Services, 2007). Research suggests that substance use during adolescence facilitates risk of other outcomes, such as risky sexual behavior and violence, and could possibly predict substance misuse later in life (Ellickson et al., 2009). This is also consistent with previous research from two cohort studies that found strong associations between drinking, illicit drug use and sexual risk behaviors, mostly among girls (Jackson et al., 2012a, 2012b, 2012c). Consequently, programs for adolescent drug abuse and sexual risk behaviors have been developed in different contexts, such as Familias Unidas (Estrada et al., 2015) (family-based), Keep Safe (Kim et al., 2013) (foster-care), and Positive Action (Beets et al., 2009) (school-based).

Research suggests that school-based programs are most effective when teaching social and personal skills, such as improvement of communication, assertiveness, decision-making, self-control (in conflict situations), coping skills (Griffin et al., 2006), moral development and clear identification of which behaviors are positive, rather than focusing solely on negative aspects of adverse situations (Beets et al., 2009). To make best use of limited human and financial resources, research emphasizes the importance of school-based preventive interventions that are evidence based. This means that an evaluation study has been conducted that indicates the program's effectiveness (Sloboda et al., 2008). A European prevention program, *Unplugged* was adapted for implementation in Brazilian public schools as part of a joint initiative overseen by the Brazilian Ministry of Health (BMH) and the United Nations Office of Drugs and Crime (Kreeft et al., 2009). The program, based on the Model of Global Social Influence (Sussman et al., 2014), sought to prevent alcohol and other drug use by enhancing personal and interpersonal skills while trying to minimize the impact of social influences by transforming beliefs and normative perceptions (Giannotta et al., 2014).

Even though school-based prevention programs can be valuable to reach a large number adolescents before the onset of substance use and sexual activity, their effectiveness still engenders a lot of discussion (Strøm et al., 2014). Multiple studies on drug prevention programs have reported effects on sexual behavior worldwide (Ellickson et al., 2009; Finer, 2010; Li et al., 2011; McNeal et al., 2004; Shek & Yu, 2011; Stanton et al., 1998). However, research has found inconsistent or limited effects of these kinds of school-based interventions (Jackson et al., 2012a, 2012b, 2012c). In Brazil, little is known about evidence-based drug use prevention programs in the school environment (Pereira et al., 2016). In prior research, the *#Tamojunto* program found to have adverse effects on reported rates of alcohol consumption (Sanchez et al., 2017, 2018). To addresses the need for further evidence, we evaluated the effects of *#Tamojunto* on the prevalence of sexual risk behaviors among adolescents in a large sample. We hypothesized that this school-based program would protect adolescents from engaging in condomless sex, compared to adolescents who did not receive the prevention program.

Method

Study Design

The present study used data from a randomized controlled trial of the school-based drug prevention program *#Tamojunto,* funded by the BMH. *#Tamojunto* was conducted with a representative sample of 7th and 8th-grade students (ages 11–15) from 72 public elementary schools in six Brazilian cities between 2014 and 2015. The cities and the surrounding areas included the Federal District, Florianópolis, Fortaleza, São Bernardo do Campo, São Paulo e Tubarão, located in four states of Brazil. The trial was registered at the Brazilian Ministry of Health's Register of Clinical Trials, number RBR-4mnv5g. The protocol is publicly available at (http://www.ensaiosclinicos.gov.br/rg/?q=tamojunto). The study protocol was reviewed and approved by the Ethics Committee of the Universidade Federal de São Paulo (CEP protocol: #473.498). This study was financed by the Brazilian Ministry of Health (TED 89/2014) and in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior—Brasil (CAPES)—Finance Code 001.

Schools were randomized into intervention and control groups. Students in intervention schools received 12 *#Tamojunto* sessions during the first semester of 2014, while the control schools did not offer any program. Sexual

risk behaviors, drug use and sociodemographic characteristics were evaluated in both groups using a structured, anonymous and self-reported questionnaire. For this study, we analyzed secondary data related to sexual risk behaviors. Baseline data were collected concomitantly in both groups of schools two weeks before program implementation (February 2014). After completion of the program, there were two follow-up assessments with the same questionnaire completed by all students. The two follow-ups were 9 months (November 2014) and 21 months after the baseline assessment (November 2015), respectively. The *#Tamojunto* program was based on the European program called *Unplugged* (Pedroso et al., 2015). As in the previous international *Unplugged* study, the same follow-up points (at 9 and 21 months) were used (Gabrhelik et al., 2012). A school year (equivalent to 9 months) was chosen since it was the maximum time interval within the same school year. For the second follow-up point, 21 months was chosen in order to establish a regular period of a year (12 months) after the first follow-up.

Participants

Depending on the size of the city in each of the participating municipalities, between 4 and 30 schools were randomly selected from all public middle schools in these locations. To identify schools, we used a list of nationally registered schools from the Instituto Nacional de Estudos e Pesquisas Educacionais (INEP—Instituto Nacional de Estudos e Pesquisas Educacionais, 2009). From the selected schools, a second simple random selection process was used to designate the control and intervention schools with a ratio of 1:1 by county.

The sample size was based on an equation from Lwanga and Lemeshow (1991) for the purpose of estimating power for recent binge drinking, the primary outcome of the *#Tamojunto* trial. For power of 80%, a significance level of 5% and a difference between groups of 1.5 percentage points (i.e., from 5 to 3.5%), we estimated that the sample size needed for each study arm was 2835. To account for loss-to-follow-up and for a high intraclass correlation, the sample was increased by 50%. This was based on results of a previously conducted pilot study on absences of enrolled middle school students (Sanchez et al., 2016). The resulting sample consisted of 4253 participants in each arm, totaling 8506 adolescents.

At each of the intervention schools, all 8th-grade classes were invited to participate in the *#Tamojunto* program and one teacher for each class received training. In Fortaleza, Santa Catarina and Tubarão, 7th-grade classes from the selected schools were also included for two reasons: first, these cities were in the process of changing the age of students assigned to each grade and; secondly, the State Education Secretariat requested the inclusion of the 7th-grade classes in the study. Details on sampling methods have been published previously (Sanchez et al., 2017, 2018) (see Fig. 1).
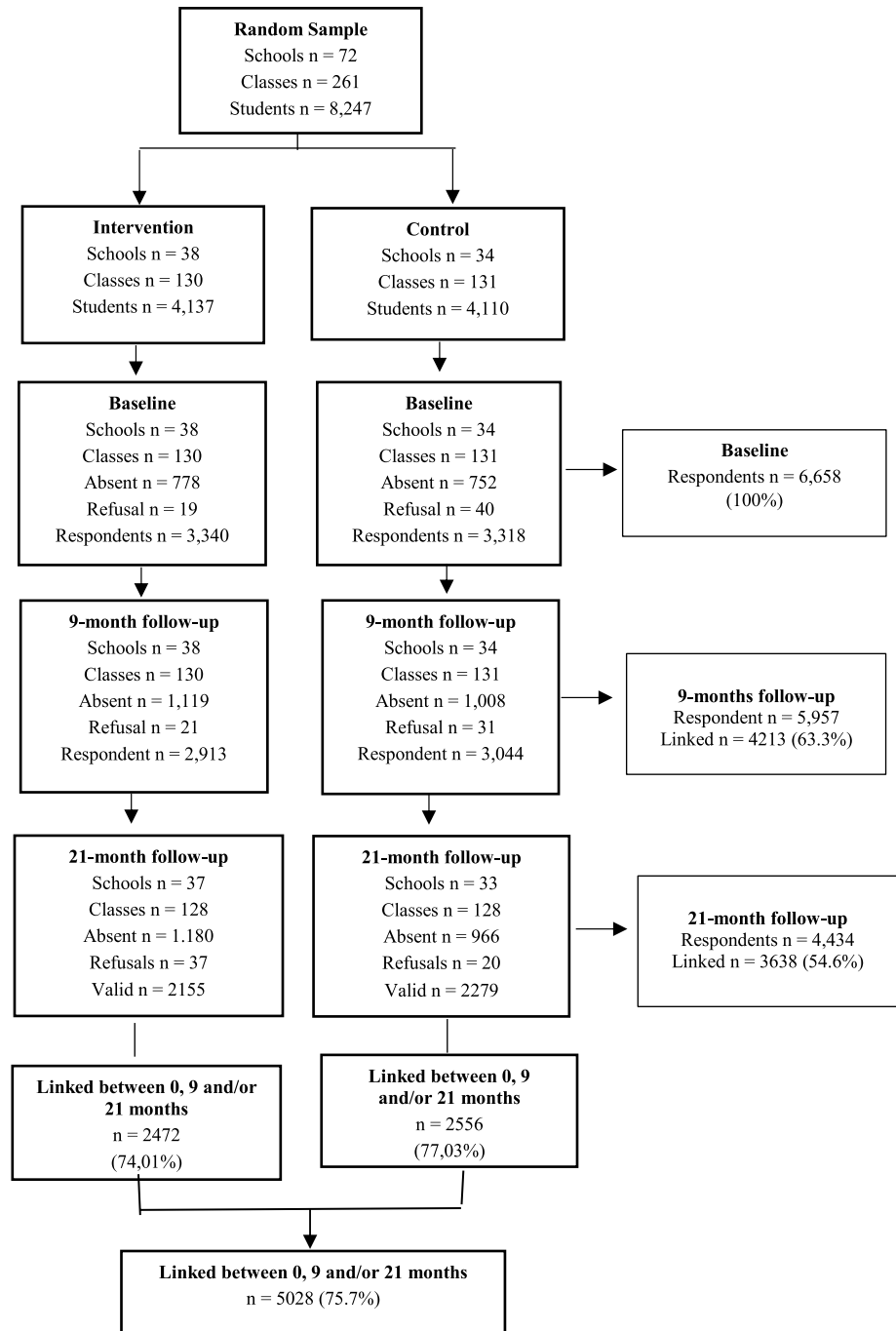
Intervention

The schools in the intervention group received 12 once a week *#Tamojunto* sessions, while the control schools received no intervention. The 12 50-minute *#Tamojunto* classroom sessions were guided by trained teachers. *#Tamojunto* is an adapted version of the Unplugged program *Unplugged* is a drug prevention program developed by researchers from the European Drug Addiction Prevention Trial (EU-DAP) group (Kreeft et al., 2009). It uses a social influence approach and addresses social and personal skills, knowledge, and normative beliefs (Vigna-Taglianti et al., 2014). Of the 12 sessions, four classes focused on attitudes and knowledge about drugs, four classes on interpersonal skills (e.g., expression of feelings) and four classes on intrapersonal skills (e.g., practicing assertiveness and coping strategies) (Kreeft et al., 2009). A teacher's manual provided information about class procedures, objectives, required materials, as well as tips and activities to be followed. A student manual outlined activities to be covered by the teacher in each class. Both manuals are freely available in several languages from the website www.eudap.net.

The English materials were translated and adapted into Brazilian Portuguese, with adaptations made to idiomatic expressions and to some activities. The BMH team performed the transcultural adaptation and was responsible for implementation of the program, which was not supervised by the European developers.

Middle school teachers delivered the intervention. As a first step, BMH staff attended an *Unplugged* program training session that was conducted by the European developers (the master trainers from the EU-DAP Intervention Planning Group) at an international workshop. Subsequently, the BMH team conducted a 16-h-long training with the teachers (Sanchez et al., 2017). At the end of each class, the teachers completed a fidelity questionnaire to monitor the amount of the program that was offered in each class. To guarantee fidelity, teachers received monthly supervision from coaches from the BMH who delivered the initial training. Supervision was carried out by e-mail, telephone or in person with the goal of assisting in class preparation, verifying program classes were delivered and troubleshooting any possible difficulties encountered by the teachers. All 12 lessons in the program were completed by 89% of the classes. The other 11% of the classes received between four and eleven lessons (Medeiros et al., 2016). All classrooms were included in the analysis.

Fig. 1 Flowchart of the *#Tamo-junto* controlled randomized trial, 2014/2015


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                        ┌─────────────────────────┐
                        │    Random Sample        │
                        │    Schools n = 72       │
                        │    Classes n = 261      │
                        │    Students n = 8,247   │
                        └─────────────────────────┘

        ┌─────────────────────┐            ┌─────────────────────┐
        │   Intervention      │            │      Control        │
        │   Schools n = 38    │            │   Schools n = 34    │
        │   Classes n = 130   │            │   Classes n = 131   │
        │   Students n = 4,137│            │   Students n = 4,110│
        └─────────────────────┘            └─────────────────────┘

        ┌─────────────────────┐            ┌─────────────────────┐            ┌─────────────────────┐
        │     Baseline        │            │     Baseline        │            │     Baseline        │
        │   Schools n = 38    │            │   Schools n = 34    │            │ Respondents n = 6,658│
        │   Classes n = 130   │            │   Classes n = 131   │            │      (100%)          │
        │   Absent n = 778    │            │   Absent n = 752    │            └─────────────────────┘
        │   Refusal n = 19    │            │   Refusal n = 40    │
        │   Respondents n = 3,340│         │   Respondents n = 3,318│
        └─────────────────────┘            └─────────────────────┘

        ┌─────────────────────┐            ┌─────────────────────┐            ┌─────────────────────┐
        │  9-month follow-up  │            │  9-month follow-up  │            │  9-months follow-up │
        │   Schools n = 38    │            │   Schools n = 34    │            │ Respondent n = 5,957│
        │   Classes n = 130   │            │   Classes n = 131   │            │ Linked n = 4213 (63.3%)│
        │   Absent n = 1,119  │            │   Absent n = 1,008  │            └─────────────────────┘
        │   Refusal n = 21    │            │   Refusal n = 31    │
        │   Respondent n = 2,913│          │   Respondent n = 3,044│
        └─────────────────────┘            └─────────────────────┘

        ┌─────────────────────┐            ┌─────────────────────┐            ┌─────────────────────┐
        │  21-month follow-up │            │  21-month follow-up │            │  21-month follow-up │
        │   Schools n = 37    │            │   Schools n = 33    │            │ Respondents n = 4,434│
        │   Classes n = 128   │            │   Classes n = 128   │            │ Linked n = 3638 (54.6%)│
        │   Absent n = 1.180  │            │   Absent n = 966    │            └─────────────────────┘
        │   Refusals n = 37   │            │   Refusals n = 20   │
        │   Valid n = 2155    │            │   Valid n = 2279    │
        └─────────────────────┘            └─────────────────────┘

        ┌─────────────────────┐            ┌─────────────────────┐
        │ Linked between 0, 9 │            │ Linked between 0, 9 │
        │   and/or 21 months  │            │   and/or 21 months  │
        │     n = 2472        │            │     n = 2556        │
        │     (74,01%)        │            │     (77,03%)        │
        └─────────────────────┘            └─────────────────────┘

                ┌───────────────────────────────────────────┐
                │  Linked between 0, 9 and/or 21 months      │
                │           n = 5028 (75.7%)                 │
                └───────────────────────────────────────────┘
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Measures

Data collection related to drug use and the mediators was carried out using an instrument developed and tested by EU-DAP that has been used in prior studies of *Unplugged* (Faggiano et al., 2008). In our translated and version adapted to Portuguese, there were substitutions of some questions. The replacements were based on questions from standard questionnaires used in Brazil. These questionnaires included the World Health Organization's questionnaire for drug use among students (Carlini et al., 2010) and the Brazilian Ministry of Health's Pesquisa Nacional de Saúde do Escolar questionnaire, which is used regularly to evaluate middle school students' health risk behaviors, such as sexual behaviors and bullying (IBGE—Instituto Brasileiro de Geografia e Estatística, 2013). Because we used single questions (not scales) about substance use and sexual behaviors, it was not possible to evaluate their reliability. Despite this, we culturally adapted these questions in

order to improve their validity (Prado et al., 2016). For substance use, our questionnaire was used to assess alcohol, tobacco, marijuana, and inhalant use. Also, we assessed binge drinking (the use of ≥ 5 doses of alcohol during a two-hour period) (Sanchez et al., 2017).

Sexual Risk Behaviors

Our primary topic of interest was sexual risk behaviors, which was measured with four items. Lifetime sex was measured by asking "Have you ever had a sexual relationship?" (yes/no). Condomless sex was measured by "When you have sex, do you use condoms?" with responses "I have never had sex," "always," "sometimes" and "never," which was collapsed into binary responses (yes/no) by grouping "sometimes" and "never" as "yes" and "I have never had sex" and "always use" as "no." We added the response "sometimes" into the "yes" group because it reflects irregular condom use behavior, which is an unsafe behavior. Non-cases were both students who never engaged in sexual activity and students who had used condoms (as use of condoms represents the absence of risk). Sex in the past month was measured by "In the past 30 days, how many times have you had sex?" with responses "I have never had sex," "not once," and "__number of times." In this case, we also used the response "__number of times" to form the "yes" group and merged the responses "I have never had sex" and "not once" to form the "no" group. Finally, condomless sex in the past month was measured by "In the past 30 days, have you ever had sex without a condom?" with response categories "I have never had sex," "no," and "yes" grouped into a binary response (yes/no). Responses "I have never had sex" and "no" represented the "no" group.

Socioeconomic Status

Socioeconomic status (SES) was evaluated using the Associação Brasileira de Empresas de Pesquisa scale (Associação Brasileira de Empresas de Pesquisa—ABEP, 2012), which considers consumer goods and head of the family's education level. This scale categorizes the student into socioeconomic status categories from "A" to "E," where "A" is the highest.

For the follow-up assessments, questionnaires were matched using each student's secret code. These codes allowed the researchers to compare individual questionnaires at different follow-up points in the study, but protected participants by preserving anonymity and confidentiality, which is essential when studying illicit behaviors (Galanti et al., 2007). It is important to note that participation was not mandatory. Students could choose to return a blank questionnaire. At the end, to avoid being identified, all the students from the same classroom placed their questionnaires inside a brown envelope. In addition, in order to reduce information bias (false positives), a question related to the use of fictitious drugs (Holoten and Carpinol) was included in the questionnaires. This precaution led to the elimination of 49, 70, and 25 students from the analyses at baseline, first follow-up (at 9 months) and second follow-up (at 21 months), respectively.

Statistical Analysis

The integration of the three databases from baseline and follow-ups was performed by pairing a secret code composed of seven letters and one number. Each code combined the following information: name, surname, date of birth, mother's, father's and maternal grandmothers' names. Given that the code included this personal information, it could be decoded only by the student. We matched the secret codes using Levenshtein's algorithm, which identifies similarities among a set of characters (Levenshtein, 1965). School and class codes were included in the matching process.

We first performed descriptive statistics including frequencies and percentages for sociodemographic variables, alcohol use and sex behaviors. Chi-square tests were used to compare groups. Analyses were performed taking into account the multilevel structure of the data to compare the effects of the control and intervention groups on sexual risk behavior variables at 9 and 21 months follow-up, adjusting for age, group, grade, site, SES, baseline sexual risk behavior status, and co-occurrence with alcohol consumption. Also, we examined alcohol use as a mediator of the intervention's effect on sexual risk behaviors. We employed a procedure called Full Information Maximum Likelihood (FIML) to handle missing data and account for the intention-to-treat paradigm, which means that the effect was estimated among all participants who started the study regardless of their loss to follow-up over time. FIML estimates a likelihood function for each individual based on the variables that are present so that all the available data are used. The analyses were stratified by gender.

To deal with the multilevel structure of the data (children nested in schools), we used a multilevel modeling approach (Muthén & Muthén, 2012). The maximum likelihood estimator was used for all the analyses with robust standard errors (MLR). The MLR accounts for the hierarchical structure of the data and clustering of students within schools (Murray et al., 2004). Subsequently, the standard error was computed taking into account non-independence of observations due to cluster sampling using a sandwich estimator (Asparouhov, 2006) with the TYPE = Complex command in the analysis command in conjunction with the CLUSTER options of the variable command in Mplus version 8.4 (Asparouhov, 2006) in Mplus version 8.4. The level of significance was set at 5%.

Table 1 Distribution of baseline sociodemographic characteristics among students participating in the #Tamojunto randomized controlled trial from 2014 to 2015 ($N=6391$)

	Total ($N=6.391$)	Intervention ($n=3.243$)	Control ($n=3.148$)	p^a
Sex				.56
Male	3130 (49.0%)	1600 (49.3%)	1530 (48.6%)	
Female	3261 (51.0%)	1643 (50.1%)	1618 (51.4%)	
Age group				.01
11–12	3343 (52.3%)	1643 (50.7%)	1700 (54.0%)	
13–15	3048 (47.7%)	1600 (49.3%)	1448 (46.0%)	
Socioeconomic status[a]				.22
A	244 (3.8%)	125 (3.9%)	119 (3.8%)	
B	2467 (38.7%)	1261 (39.0%)	1206 (38.4%)	
C	3343 (52.4%)	1704 (52.7%)	1639 (52.2%)	
D/E	322 (5.1%)	145 (4.5%)	177 (5.6%)	
Grade in school				
7th	964 (15.1%)	411 (12.7%)	553 (17.6%)	< .01
8th	5427 (84.9%)	2832 (87.3%)	2595 (82.4%)	
Site				< .01
Brasília	557 (8.7%)	283 (8.7%)	274 (8.7%)	
Florianópolis	885 (13.9%)	397 (12.2%)	488 (15.5%)	
Fortaleza	543 (8.5%)	288 (7.0%)	315 (10.0%)	
SBC[b]	954 (14.9%)	534 (16.5%)	420 (13.3%)	
São Paulo	3122 (48.9%)	1630 (74.3%)	1492 (69.6%)	
Tubarão	330 (5.1%)	171 (5.3%)	159 (5.1%)	

Comparisons between groups were calculated using the chi-square test

[a]SES—Socioeconomic status was classified according to ABEP, in which A is higher status and D/E status lower status

[b]São Bernardo do Campo

Results

Descriptive characteristics of the students participating at baseline ($n=6391$) are presented by group in Table 1. Significant differences between the intervention and control groups were observed for age, grade in school and intervention sites ($p < .05$). Both groups were homogenous with respect to gender and socioeconomic classification on the ABEP scale at baseline ($p > .05$). The adolescents' ages ranged from 11 to 15 years, with a mean age of 12.6 ± 0.8 years, and 51.0% were female.

Table 2 displays results related to the prevalence of sexual risk behaviors at each follow-up period by group. The prevalence of lifetime sex at baseline was almost identical, 12.39% and 12.43% in the intervention and control groups, respectively. Over time, the prevalence for this outcome reached 16.7% and 14.7% at 9 months and 27.4% and 23.2% at 21 month follow-up, in the intervention and control groups, respectively. *#Tamojunto* was associated with a higher likelihood of lifetime sex at 21 months (OR 1.27, 95% CI [1.03, 1.56]).

The results of the stratified analyses by gender indicated that the prevalence of reported sex was higher among boys than among girls (Table 3). For instance, regarding lifetime sex, in the intervention group, the prevalence at baseline, 9 month follow-up and 21-month follow-up was 15.3%, 24.9% and 36.4% for boys and 9.7%, 8.4% and 18.9% for girls, respectively. Also, the likelihood of lifetime sex for girls was 33% (OR 1.33, 95% CI:[1.00, 1.76]) higher at 21-month follow-up in the intervention group when compared to students in the control group.

Other results presented in Table 3 display unintended effects of the #Tamojunto program on girls. Among girls, being in the intervention group was associated with a 76% and 64% higher likelihood (OR 1.76, 95% CI [1.13, 2.74] at 9 months; OR 1.64, 95% CI [1.07, 2.50], at 21 months) of having had sex in the last month, as measured at 9 months and having condomless sex in the last month at the 21-month follow-up assessment, compared to the control group.

Table 2 Effects of a randomized controlled trial of the #*Tamojunto* program on the distribution of adolescent sexual behaviors in 2014 and 2015

	Baseline				Time								Effect of #Tamojunto	
	Intervention		Control		9 months				21 months				9 months	21 months
					Intervention		Control		Intervention		Control		Odds ratio[a] (95% CI)	Odds ratio[a] (95% CI)
	N	%	N	%	N	%	N	%	N	%	N	%		
Ever had sex (lifetime)	395	12.39	385	12.43	336	16.7	318	14.7	480	27.4	426	23.2	0.99 (0.76–1.30)	**1.27 (1.03–1.56)**
Ever had condomless sex (lifetime)	142	4.5	146	4.7	110	5.5	124	5.7	143	8.2	140	7.6	0.87 (0.64–1.18)	1.08 (0.78–1.48)
Sex in past month	256	8.1	254	8.3	212	10.6	182	8.5	266	15.3	250	13.7	1.19 (0.90–1.58)	1.14 (0.87–1.49)
Condomless sex in past month	119	3.7	130	4.2	94	4.7	93	4.3	148	8.5	125	6.8	0.97 (0.69–1.38)	1.31 (0.90–1.90)

Bold font indicates statistical significance $p < .05$

Sex in lifetime—defined as "yes" to the question "Have you ever had sexual intercourse ?"; Condomless sex in lifetime—referred to "sometimes use" or "never use" in response to the question "When you have sexual intercourse, do you use condom?"; Sex in the past month—defined as "yes" to the question "Have you had sex at the last month?"; Condomless sex in month—indicated by "yes" to the question "Have you had sex without condom at the last month?"; [a] Included the total sample in the analysis.

The analysis was conducted with Full Information Likelihood, while adjusting for age group, grade, site, socioeconomic status and baseline sexual status and alcohol use

Attrition

As expected, students who missed both follow-up assessments showed a significantly higher prevalence of all sexual risk behaviors at baseline compared to students who were participated in at least one follow-up assessment. For instance, while the prevalence of lifetime sex was 20.3% among students whose data did not have follow-up data, it was 10.2% among students with data from at least one follow-up point ($p < .001$). For sex in the past month, the prevalence ranged from 6.8% among students who participated in at least one follow-up to 12.9% among students only participating at baseline ($p < .001$). Alcohol use in the past month was more common among students with only baseline data compared to students with paired data, except for students who reported not having drunk in the last month. Regarding differences between the intervention and control groups, there were more students who could not be followed up from the intervention group than from the control group (56.6% vs. 43.4%). Regarding age group, younger students (11–12 years old) had more data both at baseline and at least one follow-up point than did the older students (13–15 years old). Finally, no differences were found by gender. In the supplementary material, we present information about regular alcohol consumption and sexual risk behaviors (Table S1), an analysis of the pattern of participant attrition (Table S2) and analyses in which alcohol use is tested as a potential mediator of the intervention's effect on sexual risk behaviors (Table S3). Regarding the missing data on students who could not be followed up, data were not imputed since they were not missing at random.

Discussion

In this study, we found an iatrogenic effect of the intervention on engaging in lifetime sex at 21-month follow-up. Additionally, the study suggested a potential detrimental effect of the program on girls. Girls in the intervention group reported a higher likelihood of having engaged in sex in the last month as well as engaging in condomless sex in the last month. Taking these results together, the implementation of this school-based program as a potential policy initiative of the Brazilian government triggers concerns due to potential increases in girls' sexual behaviors and condomless sex behaviors following participation.

The #*Tamojunto* program in Brazil also found negative effects on non-sexual behavioral outcomes in previously published studies, with participation leading to a 30% increase in alcohol initiation at 9-month follow-up (Sanchez et al., 2017) and a 13% increase at 21-month follow-up. The results also showed significant differences between the intervention and control groups in the use of inhalants (Sanchez et al., 2018).

Table 3 Sex-stratified results of the effects of the #Tamojunto program on the distribution of adolescent sexual behaviors in 2014 and 2015

	Gender	Time												Effect of #Tamojunto	
		Baseline				9 months				21 months				9 months	21 months
		Intervention		Control		Intervention		Control		Intervention		Control		Odds ratio[a] (95% CI)	Odds ratio[a] (95% CI)
		N	%	N	%	N	%	N	%	N	%	N	%		
Ever had sex (lifetime)	Male	237	15.3	241	16.1	241	24.9	231	23.2	300	36.4	278	31.8	0.99 (0.75–1.30)	1.19 (0.90–1.57)
	Female	158	9.7	144	9.0	83	8.4	83	7.5	169	18.9	137	14.9	0.97 (0.62–1.53)	**1.33 (1.00–1.76)**
Ever had condomless sex (lifetime)	Male	91	5.8	101	6.8	79	8.1	91	9.1	88	10.7	90	10.3	0.88 (0.63–1.24)	1.00 (0.70–1.44)
	Female	51	3.2	45	2.8	27	2.7	33	3.0	50	5.6	44	4.8	0.79 (0.44–1.41)	1.17 (0.75–1.83)
Sex in past month	Male	161	10.5	151	10.2	142	14.8	133	13.4	158	19.2	161	18.5	1.00 (0.73–1.35)	1.00 (0.70–1.29)
	Female	95	5.9	103	6.5	62	6.3	47	`4.2	100	11.3	81	8.8	**1.76 (1.13–2.74)**	1.45 (0.97–2.18)
Condomless sex in past month	Male	71	4.6	72	4.8	55	5.7	63	6.4	76	9.2	74	8.4	0.78 (0.52–1.18)	1.06 (0.63–1.80)
	Female	48	2.9	58	3.6	35	3.5	30	2.7	69	7.7	45	4.9	1.41 (0.90–2.21)	**1.64 (1.07–2.50)**

Bold font indicates statistical significance $p < .05$

Sex in lifetime—defined as "yes" to the question "Have you ever had sexual intercourse ?"; Condomless sex in lifetime—referred to "sometimes use" or "never use" in response to the question "When you have sexual intercourse, do you use condom?"; Sex in the past month—defined as "yes" to the question "Have you had sex at the last month?"; Condomless sex in month—indicated by "yes" to the question "Have you had sex without condom at the last month?"; Unsafe sex was based on students who were already sexually active; [a] Included the total sample in the analysis. The analysis was conducted with Full Information Likelihood, while adjusting for age group, grade, site, socioeconomic status and baseline sexual status and alcohol use

Another study with high school students, in the U.S., also found that, when associated with substance use, sexual risk behaviors were more likely to occur among females (Connell et al., 2009). For adolescents, this co-occurrence may reflect a strategy to manage distress in their relationships, e.g., due to lack of bonding with peers or to cope with feelings of inadequacy (Bellis et al., 2008). These findings suggest that it is possible that between-group differences in sexual behaviors could be causally related, in part, due to the intervention's adverse effect on substance use behaviors. In our study, we tested alcohol use as a mediator of the effect of the intervention on sexual behavior. However, alcohol use was not a statistically significant mediator, and we could not confirm the hypothesis that there was an indirect effect. Therefore, we conclude that it is more likely that the program is causally associated with these negative changes in sexual behaviors.

An evaluation of *#Tamojunto's* fidelity through semi-structured interviews with the teachers who taught the program showed that they were struggling to deliver the lessons in the regular 50-minute classroom period and took the liberty to make program adaptations, omitting important content, which could have compromised the expected results (Brasil-Ministério da Saúde, 2018). Complaints regarding the amount of time needed to implement the intervention were not surprising. However, despite a large proportion of teachers who implemented the *Positive Action Program* in Chicago and reported that they also struggled to deliver the lessons as intended, that program had positive effects on sexual behavior (Li et al., 2011). In addition, another program called *All Star* investigated if different delivery conditions would affect their results. Neither the schools that received the program delivered by teachers or by specialists showed much impact on postponing the initiation of students drinking alcohol or engaging in sexual intercourse (McNeal et al., 2004).

Furthermore, it is important to consider the fact that many Brazilian students have poor reading skills. According to the Programme for International Student Assessment, an international comparative study, 50.1% of 15-year-old Brazilian students attained level 2 or above in reading skills. In contrast, only 13% of students in Finland were below level 2 in reading skills. The scale consists of 7 levels (1b, 1a, 2, 3, 4, 5 and 6) in ascending order of proficiency. At level 2, readers are able, when explicitly asked, to reflect on the general objective, or on the objective of specific details, in brief passages of text. Levels 3, 4, 5 and 6 capture students' abilities to assess the quality and credibility of information. At these levels, readers are also able to reflect and to compare the views of several authors. Regarding the "comprehension" subscale, the average for Brazil (409 points) is well below the average for the Organization for Economic Cooperation and Development (OECD) (INEP - Instituto Nacional de Estudos e Pesquisas Educacionais, 2018). It is possible that Brazilian adolescents also struggled to respond to the questionnaire.

Sexual behaviors are commonly initiated during early adolescence, and tend to increases over time with age, as part of normal development (Jackson et al., 2012a, 2012b, 2012c). However, it is important to note that engaging in sexual intercourse before the age of 16 has important implications for adolescent health (Heywood et al., 2014). In terms of reproductive outcomes, the practice of sexual intercourse during early adolescence puts this population at higher risk of unwanted pregnancy, abortion, and STDs (World Health Organization, 2016), likely due to having more sexual partners (Sandfort et al., 2008). In terms of social implications, teenage pregnancy has been associated with school dropout for girls after becoming mothers, which has serious consequences for educational attainment, income, and social mobility (Florescu et al., 2016). A Youth Risk Behavior Survey in Korea found that early initiation of sexual intercourse was associated with alcohol and drug abuse, which tend to put teenagers at higher risk of not only those outcomes (stated above) but also to develop antisocial characteristics which, together, potentially lead them to consider and/or to attempt suicide (Kim & Kim, 2010). Therefore, from a public policy perspective, it is crucial to consider these findings when implementing school programs intended to prevent related risk behaviors (such as drug use and violence), but that could simultaneously have a negative impact on sexual health outcomes.

No clear effects of *#Tamojunto* were observed for lifetime condomless sex. To our knowledge, this outcome was not evaluated when the *Unplugged* program was implemented in Europe, in spite of the fact that Problem Behavior Theory (the most influential theory guiding *Unplugged*) states that early sexual intercourse is closely related to the use of alcohol, tobacco and other illicit drug use as well as other deviant behaviors (Vadrucci et al., 2016). Also, a number of studies have demonstrated associations between sexual risk behaviors and substance use during adolescence (Jackson et al., 2012a, 2012b, 2012c; Marshall, 2014).

Another school-based drug abuse prevention program called *Life Skills Training* was evaluated for subsequent sexual risk behaviors. It showed that students who received the intervention were less likely to engage in HIV risk behaviors (Griffin et al., 2006). Additionally, the *Positive Action Program*, a multicomponent school-based social and character development program, was developed to address risk behaviors, such as substance use, violence and voluntary sexual activity. It revealed that lifetime sexual activity was lower for students attending the intervention schools (Beets et al., 2009). Those findings contrast with our study that suggested negative effects on engagement in sex in the last month and condomless sex in the last month among girls. Social Learning Theory, the basis of the interactive methods used in working groups in *Unplugged*, postulates a dialectical relationship between the environment, behavior

and psychological processes. When students in our program were in small working groups, they experienced difficulties in sharing emotions. Learning to express divergent opinions in groups may have led the adolescents to reflect on social pressures they face and to improve their skills in managing such situations. Additionally, concepts from the Health Belief Model were used to structure activities about decision making (Vadrucci et al., 2016). It is possible that these activities also improved participants' self-confidence, which may have carried over to other contexts, such as in their sexual lives.

Topics such as sex and drugs are considered sensitive health behaviors (Brown & Wissow, 2009). For this reason, sometimes adolescents may have concerns and/or feel shy talking about intimate aspects of their lives. Thus, one explanation of these findings could be that *#Tamojunto* increased students' willingness to open up and therefore increased the likelihood of reporting their own sexual behaviors, i.e., exposure to *#Tamojunto* might have led to more open, truthful and less taboo-affected reporting at the follow-up assessments. Furthermore, our study also used confidential self-report questionnaires, which are the golden standard for data collection in effectiveness studies that evaluate behaviors among students. *#Tamojunto* was an effectiveness study, which means that the study was conducted under real life conditions. Moreover, the *#Tamojunto* program was carried out as a government initiative, through an official agreement between the Ministry of Health and the Education Departments of each state and municipality, though they had little control over its implementation. Although these real life conditions resulted in several obstacles to its implementation, identifying them is important to improving prevention programs.

Some limitations merit attention. Of central concern are the participation rates; there were a large number of students who were absent at baseline and/or at follow-up. A national survey conducted in Brazil revealed that approximately 20% of public school students are absent each day (IBGE—Instituto Brasileiro de Geografia e Estatística, 2013). Furthermore, there was attrition throughout the study and therefore results cannot be extrapolated to all students. However, attrition is an expected limitation in RCTs, and has also been a common problem in other school-based prevention studies (Ariza et al., 2013; Newton et al., 2010). Another potential limitation is that self-reported responses may be subject to social desirability bias. Also, a follow-up assessment at the time of intervention completion would have been desirable. Nonetheless, a question about a fictitious drug allowed us to discard questionnaires with over-reporting bias from the analysis. Lastly, our study does not explain how differences in boys' and girls' behaviors may have influenced these findings; future studies could shed more light on reasons for the gender differences we observed. Despite these limitations, strengths include the randomized nature of the study and the involvement of six cities in different regions of Brazil increases the generalizability of the findings.

In summary, the results indicate that *#Tamojunto* may not be effective for the prevention of sexual risk behaviors, especially among girls. Future research that builds from these findings should prioritize the development and evaluation of other sexual risk prevention programs in the Brazilian context.

Declarations

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

Human Participants and/or Animal Subjects 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 Helsinki Declaration 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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