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Does the Brazilian version of the strengthening families program (Familias Fortes) reduce adolescent substance use and change parental behavior? Evidence from a 2-year follow-up study

Zila M. Sanchez[1,4*], Sheila C. Caetano[2], Patrícia P. O. Galvão[1], Fabiane A. Gubert[3], Lidiane N. Rebouças[3], Luis Eduardo Soares-Santos[1] and Juliana Y. Valente[1]

Abstract

Background The Brazilian adaptation of the Strengthening Families Program (SFP), known as Famílias Fortes (FF-BR 10–14), has demonstrated positive short-term effects on parental behavior. This study aims to evaluate the 12- and 24-month follow-ups of the FF-BR 10–14, focusing on parental outcomes and substance use prevention.

Methods This is a parallel-cluster randomized controlled trial (RCT) involving 1610 participants (805 adolescents aged 10–14 and 805 caregivers). Conducted across 60 Social Assistance Reference Centers (SARC) in 12 municipalities in Brazil, the trial evaluates the effectiveness of the FF-BR 10–14 program. This study presents data collected at three time points: baseline, 12 and 24 months of follow-up. Multilevel mixed-effects models assessed the program effects on parental and adolescent outcomes (drug use and family behavior), with adjustments for sociodemographic factors.

Results The results reveal no statistically significant differences between the groups in terms of adolescent drug use after either follow-up. However, participating in the program shows a reduction in negligent parental style (aOR 0.46, 95%CI 0.22;0.97), parental binge drinking (aOR 0.24, 95%CI 0.08; 0.74), as well as an increase in parental ability to set clear rules regarding their children's drug use (β 0.43, 95%CI 0.03; 0.83) and an improvement in adolescents' skills to resolve family conflicts (β 0.79, 95%CI 0.11; 1.46) and to manage stress (β 0.65, 95%CI 0.16; 1.15).

Conclusion The Famílias Fortes program shows positive effects on mediators, such as parenting practices and adolescent coping skills, but not on the primary outcomes of adolescent substance use. These findings highlight the program's role in improving the family environment and supporting prevention efforts through intermediary behaviors.

*Correspondence:
Zila M. Sanchez
zila.sanchez@unifesp.br

Full list of author information is available at the end of the article

Trial registration The study was registered in the Brazilian Ministry of Health Register of Clinical Trials (REBEC), under protocol no. RBR-5hz9g6z (https://ensaiosclinicos.gov.br/rg/RBR-5hz9g6z) - July 8th, 2022.

Keywords Strengthening families Program, Alcohol, Prevention, Adolescent, Parenting

Introduction

Substance use among adolescents is a key risk factor for various health complications, such as cancer and mental disorders, emphasizing the importance of implementing measures to prevent this behavior [1, 2]. In Brazil, the most recent school national health survey found that 63% of students aged 13–17 years have experimented with alcoholic beverages, 23% have tried cigarettes, and 13% have used illicit drugs. Alcohol intoxication presents a notable health risk, as 50% of students who consume alcohol experience episodes of drunkenness [3]. Moreover, initiating alcohol use at an early age is associated with an increased risk of substance abuse disorders and their consequences in later life [4]. Some prevention programs targeting the reduction or postponement of substance use initiation have been shown to mitigate such behaviors.

In the hierarchy of scientific evidence regarding the effectiveness of preventive interventions on substance use, family-based programs appear to have more significant effects compared to school programs aimed exclusively at adolescents [5].

The Strengthening Families Program (SFP) is an example of a family-based intervention aimed at reducing adolescent drug use by improving family relationships and promoting healthy lifestyle skills [6]. The SFP tailored for children and adolescents aged 10–14 years (SFP 10–14) has demonstrated favorable outcomes across multiple countries, with particularly noteworthy results in the United States. Extensive long-term studies spanning an average of five-year follow-ups conducted by Spoth et al. [7–9] and Riesch et al. [10]demonstrated delayed initiation and reduced frequency of alcohol and other drug use. Additionally, these studies have indicated enhancements in family cohesion and parental supervision. Nevertheless, some European and Latin American studies [11, 12] have reported no significant effects of the program on preventing drug use, especially during the 4-year follow-up period [13, 14].

In 2013, the Brazilian Government, in collaboration with the United Nations Office on Drugs and Crime in Brazil (UNODC Brazil), conducted a cultural adaptation process and launched the Brazilian version of the SFP 10–14 program, renamed Families Fortes, based on the European version of Oxford Brooks University [15]. Subsequent cultural evaluations of the Brazilian adaptation demonstrated its high level of engagement, cultural relevance, commendable objectives, and alignment with the specific needs of vulnerable Brazilian families attending governmental Social Assistance Centers [16].

Given the program's implementation as a public policy in 2021, it has become imperative to assess its effectiveness in Brazil compared to that observed in other countries, thus justifying government investment. Consequently, from 2021 to 2022, the program will undergo an effectiveness evaluation study conducted via a randomized controlled trial (RCT) [17]. The initial RCT findings, assessed six months after implementation, showed positive effects on parental behavior. Notably, there was a decrease in negligent parenting styles, an increase in non-violent disciplinary practices, and a reduction in adolescent exposure to episodes of parental drunkenness. However, no immediate effects on adolescent substance use were observed during the short-term follow-up period [17].

Given the consistent findings from multiple studies [7–10] indicating that–SFP10-14 leads to a decrease in the prevalence of adolescent drug use and delays initiation later in life, aligning with the proposed logic model, we identified the need for extended follow-up. Thus, this study aimed to assess the long-term effectiveness of the Brazilian adaptation of the Strengthening Families Program in improving parental outcomes and preventing drug use, with follow-up periods of 12 and 24 months.

Methods

Study design

This is a parallel-cluster randomized controlled trial (RCT) involving 1610 participants (805 adolescents aged 10–14 and 805 caregivers). Conducted across 60 Social Assistance Reference Centers (SARC) in 12 municipalities[1] in Brazil, the trial evaluates the effectiveness of the FF-BR 10–14 program. Randomization was performed at the SARC level within each city, with all SARCs in each city randomly assigned to either the control or intervention group (1:1). Control and intervention SARCs were equally distributed in each municipality. The inclusion

[1] Barueri/SP, Campina Grande/PB, Cascavel/CE, Carapicuíba/SP, Eusebio/CE, Fortaleza/CE, Ingá/PB, Nova Iguaçu/RJ, Pacatuba/CE, São Gonçalo do Amarante/CE, São José dos Campos/SP, Sinop/MT. Seven municipalities are located in the Northeast, Brazil's poorest region. Among those, five are small cities, with populations ranging from 17,600 to 94,000 inhabitants and HDI ranging from 0.592 to 0.788. One of these municipalities is medium-sized with a population of 402,000 inhabitants and an HDI of 0.720, while the other is a major city with 2.6 million inhabitants and an HDI of 0.754. The other five municipalities are located in the southern and central-western regions of the country, are more urban, and have populations ranging from 146,000 to 823,000 inhabitants, with HDI ranging from 0.749 to 0.807.

criteria were as follows: one parent/caregiver and at least one child or adolescent aged 10–14 years living in the same household willing to participate in the program, available to attend the seven weekly meetings, and residing within 1 km of the SARCs. Families with substantial drug use were excluded. The intervention group, consisting of parent/caregivers and children or adolescents, attended the Famílias Fortes program for seven weeks. After the study's conclusion, the control families were placed on a waiting list for future interventions. The random drawing was conducted by an external collaborator via an algorithm based on atmospheric noise available at http://www.random.org. The trial was conducted in accordance with the CONSORT (Consolidated Standards of Reporting Trials) 2010 guidelines [18].

Data collection took place at four time points: before intervention implementation (November–December 2021), six months (May–June 2022), 12 months (November–December 2022), and 24 months (November–December 2023) after the first collection. The flowchart (Fig. 1) describes the participant distribution over 24 months. The initial data collection comprised 805 families, with 371 in the intervention group and 434 in the control group. At the 12-month follow-up, 21.6% of the participants were lost, resulting in interviews with 635 families, including 295 in the intervention group and 340 in the control group. At the 24-month follow-up, 586

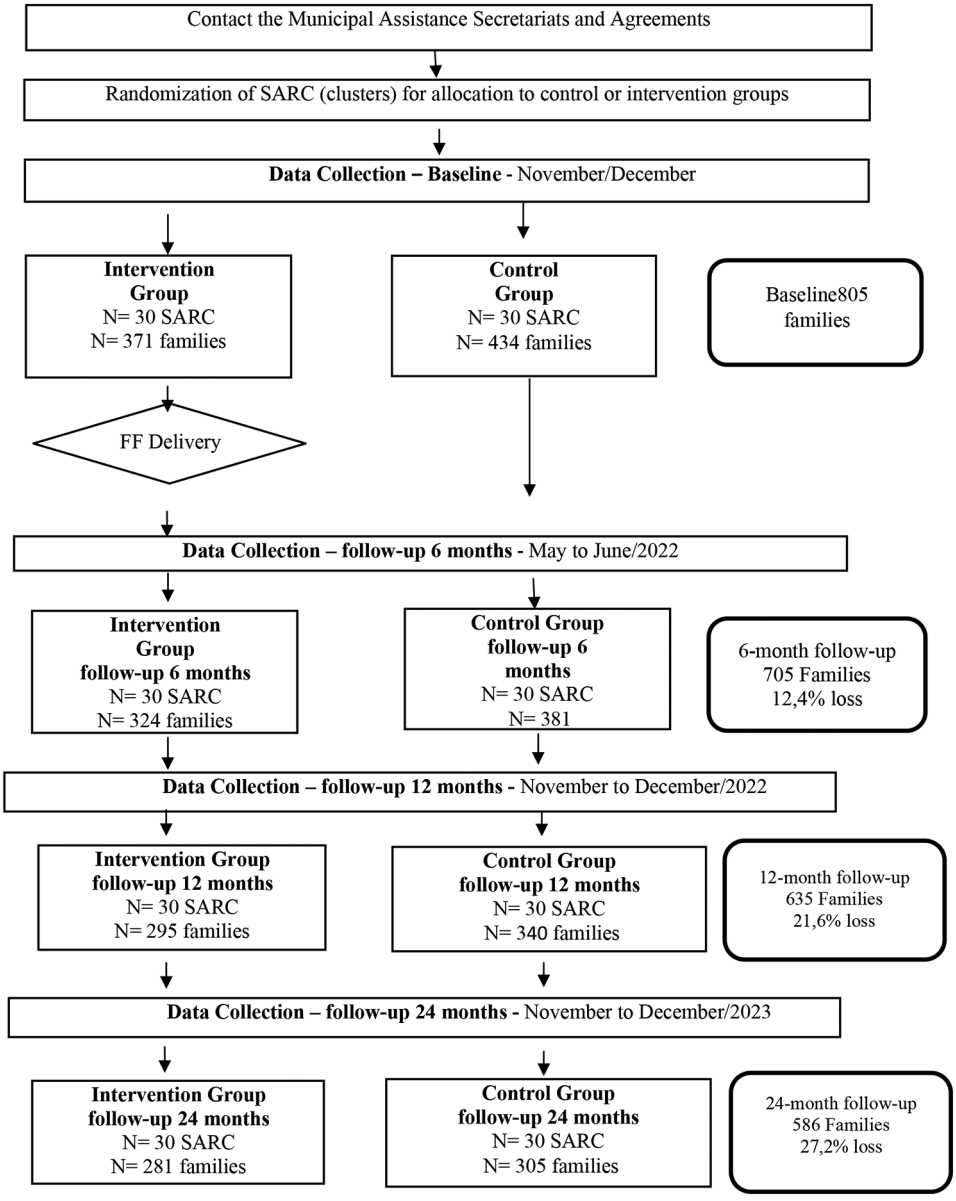

Fig. 1 Flowchart of the randomized controlled trial of the *Famílias Fortes* program

families were followed up, with 281 in the intervention group and 305 in the control arm, resulting in a 27,2% loss. The primary reasons for sample loss were changes in address and the inability to establish telephone contact. Considering that this study evaluated the long-term effects of the program, only the baseline, 12-month, and 24-month follow-ups were considered in the analysis. For short-term effects (6-month follow-up), please refer to Sanchez et al. [17]

All procedures in the current study followed the institutional norms and ethical standards of the national research committee, and the 1964 Declaration of Helsinki and further amendments. Parents/guardians completed Informed Consent Forms and adolescents completed Informed Assent Forms stating that they agreed to participate in the study.

Intervention

The Famílias Fortes Program (FF-BR 10–14) is a Brazilian adaptation of the SFP-10-14, initially developed by Oxford Brookes University in the United Kingdom [6]. It comprised seven consecutive face-to-face sessions, each lasting two hours. These sessions involved separate meetings for caregivers and children during the first hour, followed by joint family activities in the second year. The activities included discussions, games, interactive exercises, and videos depicting everyday family scenarios focusing on family relationships, parental skills, and psychosocial skills training. Snacks were provided at the end of each session.

The program was delivered by staff members at the SARC, mainly psychologists, nurses, and social workers, who underwent specialized training for program implementation. Implementer training was provided through a 25-hour distance learning course delivered online.

Instrument and measures

We used two self-reported, anonymous questionnaires administered through a smartphone application or Internet links: one designed for adolescents and the other for caregivers. Each family was assigned a unique code to facilitate linkage between the questionnaires. This coding system also enabled the identification of the respective SARC to allow multilevel analysis at the SARC level.

The instrument evaluates sociodemographic data, drug use, and family behavior. It was designed based on international instruments developed to assess SFP 10–14 [19, 20] and instruments previously used in Brazilian drug use prevention program studies [21].

Adolescent outcomes

The adolescent outcomes assessed from adolescents were socioemotional skills, perceived drug risk, and lifetime substance use.

Adolescents' socioemotional skills were assessed using the SFP 10–14 Youth Survey Questionnaire (YPSQ). This instrument is a structured self-report instrument [20], consisting of eight subscales: Parental Expectations (4 items), Quality of Parent-Child Relationship (4 items), Family problem-solving skills (4 items), Stress management skills (3 items), Family communications skills (4 items), Rules and expectations about drug use (2 items), Peer pressure skills (5 items), and Future Orientation, i.e., future planning (5 items). The scale consists of a three-point Likert scale where 'rarely or never' is scored 1 and 'most of the time or always' scored 3. A confirmatory factor analysis (CFA) was performed in the current sample to evaluate the construct validity of the YPSQ Questionnaire subscales. The analysis showed that the model fit well, as indicated by the fit indices. Factor loadings met acceptable levels (0.50 or higher), indicating that the items meaningfully contribute to defining the factor. The fit indices of the dimensional model for the **familiar communication skills** scale at the baseline. indicated a good model, with X^2 = 1.636 and p-value 0.4413, RMSEA estimate = < 0.001, RMSEA probability = 0.854, CFI = 1.000, and TLI = 1.002. The fit indices of the dimensional model for the **problem-solving skills scale** at the baseline indicated a good model, with X^2 = 0.003 and p-value 0.9535, RMSEA estimate = 0.000, RMSEA probability = 0.983, CFI = 1.000 and TLI = 1.010. The fit indices of the dimensional model for the **parental expectations** (rules) scale at the baseline indicated a good model, with X^2 = 2.834 and p-value 0.2424, RMSEA estimate = 0.023, RMSEA probability = 0.725, CFI = 0.999, and TLI = 0.996. The fit indices of the dimensional model for the **positive parental relationship** scale at the baseline indicated a good model, with X^2 = 5.747 and p-value 0.0565, RMSEA estimate = 0.049, RMSEA probability = 0.434, CFI = 0.997, and TLI = 0.990. The fit indices of the dimensional model for the **adolescent future prospective** scale at the baseline indicated a good model, with X^2 = 2.404 and p-value 0.7909, RMSEA estimate= ><0.001, RMSEA probability = 0.994, CFI = 1.000, and TLI = 1.003.

Regarding substance consumption by adolescents, the initiation (yes x no) of substance use (alcohol, cigarettes, marijuana, inhalants, and binge drinking) and risk perception (no risk to high risk) of drug use (alcohol, cigarettes, and marijuana) were evaluated using questions extracted from the Brazilian Center for Psychotropic Drugs Information (CEBRID) [22] and Substance Abuse and Mental Health Services Administration [23, 24], respectively.

Parental/caregiver outcomes

The parental outcomes evaluated were family violence, parenting styles, parental alcohol use, children's exposure to parental drug use, and parental skills.

Parental styles were analyzed in four classes (authoritative, authoritarian, indulgent, and negligent) using the Parental Demand and Responsiveness Scale [25]. This scale has six items for the demanding dimension and ten for the responsive dimension. Responses were measured on a three-point Likert scale, with higher values indicating greater perceived demand and responsiveness (0–12 and 0–20, respectively). The parenting style dimensions were established using the median split procedure, following the methodology used in previous studies [25–27]. The combined dimensions resulted in four parental style categories: authoritative (caregivers scoring high on demandingness or responsiveness), authoritarian (scoring high on demandingness and low on responsiveness), indulgent (scoring low on demandingness and high on responsiveness), and negligent (scoring low on demandingness and responsiveness). Prior psychometric evaluation of the scale in a sample of 6.391 students in the 7th and 8th grades in Brazil showed good fit: $\chi 2 = 1518.249$, $p < 0.001$, RMSEA = 0.050, CFI = 0.940, TLI = 0.929, WRMR = 2.377 [28].

Family violence (non-violent, verbal, and physical discipline) was measured using the domestic violence subscale of the World SAFE Core Questionnaire [29], which was translated and validated for Brazilian Portuguese [30]. This questionnaire has questions grouped into three subscales (Non-violent Discipline, Verbal Discipline, Physical Discipline) and asks how often caregivers have used specific disciplinary tactics, with responses rated on a 3-point scale, namely never, 1–2 times, and ≥ three times, in the previous three months. Therefore, the questionnaire resulted in three subcategories: Verbal Discipline (score from 0 to 16), Physical Discipline (score from 0 to 24), and Non-violent Discipline (score from 0 to 10); the higher the value, the greater the degree of type discipline affected. The scale also measures the total violence score produced from the sum of verbal and physical discipline scores. We conducted a CFA with the current sample to assess the construct validity of the domestic violence subscale of the World SAFE Core Questionnaire. The CFA results indicated a good model fit, as reflected by the fit indices. The fit indices of the dimensional model for the Non-violent discipline scale at the baseline indicated a good model, with $X^2 = 24.122$ and p-value 0.0002, RMSEA estimate = 0.069, RMSEA probability = 0.108, CFI = 0.995, and TLI = 0.990. The fit indices of the dimensional model for the Verbal Discipline Scale at the baseline indicated a good model, with $X^2 = 43.576$ and p-value 0.0017, RMSEA estimate = 0.038, RMSEA probability = 0.884, CFI = 0.990, and TLI = 0.985. The fit indices of the dimensional model for the Physical discipline scale at the baseline indicated a good model, with $X^2 = 383.197$ and p-value < 0,001, RMSEA estimate = 0.053, RMSEA probability = 0.226, CFI = 0.925, and TLI = 0.915.

Concerning parental alcohol use, this study assessed the frequency of alcohol consumption and the practice of binge drinking. Frequency was determined by asking, "How often do you drink alcoholic beverages?" with five response options: never, monthly, or less, 2–4 times a month, 2–3 times a week, or four or more times a week. The following question was asked to assess the dose consumed: "When you consume alcoholic beverages, how many doses do you typically drink?" Options included 2, 3 or 4, 5 or 6, 7 to 9 and 10 or more. Based on their reported frequency, binge drinking was assessed through a dichotomous categorization of respondents as either practicing or not. Binge drinking refers to the occasional consumption of five or more doses of alcohol.

The extent of the children's exposure to parental drug use was evaluated using a set of questions gauging the level of parental exposure of their children to various substances (alcohol use, alcohol intoxication, and cigarette use). For instance, one question asked, "Do you consume alcohol in the presence of your child?" with response choices ranging from never to always.

Parental skills were assessed using the SFP 10–14 Parent/Caregiver Survey Questionnaire (PCSQ) [20, 31] answered by the adolescents, consisting of 7 blocks of family behavior questions: Rules and expectations about drug use (3 items), Parental Monitoring (4 items), Parental Expectations (6 items), Quality of Parent-Child Relationship (3 items), Family problem-solving skills (7 items), Positive Parental Practices (6 items), Goal Communication (2 items). The scale consists of a three-point Likert scale where 'rarely or never' is scored 1 and 'Most of the time or always' scored 3. We conducted a CFA with the current sample to assess the construct validity of the PCSQ subscales, indicating a good model fit. The fit indices of the dimensional model for the parental monitoring scale at the baseline indicated a good model, with $X^2 = 8.924$ and p-value 0.0115, RMSEA estimate = 0.066, RMSEA probability = 0.220, CFI = 0.979, and TLI = 0.937. The fit indices of the dimensional model for the parental expectations scale at the baseline after modification indicated a good improved model, with $X^2 = 20.779$ and p-value 0.0078, RMSEA estimate = 0.045, RMSEA probability = 0.609, CFI = 0.987 and TLI = 0.976. The fit indices of the dimensional model for the Positive Parental Behaviors scale at the baseline indicated a good model, with $X^2 = 17.249$ and p-value 0.0450, RMSEA estimate = 0.034, RMSEA probability = 0.856, CFI = 0.993, and TLI = 0.989. The fit of the dimensional model for the Problem-Solving Skills scale at the baseline indicated a good model after modification with $X^2 = 36.907$ and p-value 0.0004, RMSEA estimate = 0.048, RMSEA probability = 0.546, CFI = 0.985 and TLI = 0.976.

Covariate variables

At baseline, sociodemographic data, including caregivers' and adolescents' sex (men, women, and others), age, and socioeconomic status, were collected as *explanatory variables*. The socioeconomic status (SES) of families was evaluated using the Brazilian Association of Research Companies (Associação Brasileira de Empresas de Pesquisa—ABEP) scale [32]. It assesses the household head's education level and the goods and services used, resulting in scores ranging from 1 to 100. Higher scores indicated better SES; socioeconomic classes were ranked from A (highest) to E (lowest).

Data analysis

To account for the longitudinal hierarchical structure of the data, we employed multilevel mixed-effects modeling with repeated measures. Three-level mixed-effects models (level 1: repeated-time observations nested within the subject; level 2: subject clustered within SARC; level 3: SARC itself) were used to evaluate changes in intervention outcomes after 12 months. In accounting for possible baseline differences between the control and intervention groups, a diff-in-diff approach was applied to the multilevel models. The effects of time, group, and the interaction between group and time were considered in all models, making it possible to assess different group behaviors between the assessments.

Moreover, mixed-effects models utilize maximum likelihood estimation to handle missing data by analyzing all available outcome data, regardless of completeness, aligned with the intention-to-treat (ITT) analysis [33]. We assumed that the missing data followed a Missing at Random (MAR) pattern related to other variables in the model, not just the missing variable itself. Most missing data in our study came from participants who did not respond to the follow-up assessment rather than leaving individual questions unanswered or dropping out of the intervention. Under the MAR assumption, mixed models for repeated measures yield valid and unbiased estimates, rendering additional techniques for managing missing data, such as multiple imputations, generally unnecessary [34].

All models were fitted using the STATA 17 program [35] with generalized linear mixed models (GLMM) and adjusted for sex, age, and SES of adolescents and caregivers. We included covariates based on theoretical considerations and prior literature relevant to the intervention's context. For attrition analysis, we compared families with matched data from two-time points with families who only answered the baseline questionnaire.

Results

Table 1 presents the sociodemographic characteristics of the 805 participating families (805 adolescents and 805 parents/caregivers; 1610 participants in total). At baseline, no significant differences were found in gender or age between the intervention and control groups. However, the intervention group had a higher proportion of families from lower socioeconomic classes (D/E),

Table 1 Sociodemographic characteristics of families in the Famílias Fortes study at baseline

	Total ***N*** **= 805**		**Control group** ***N*** **= 434**		**Intervention group** ***N*** **= 371**		***p*-value***
	N	**%**	***N***	**%**	***N***	**%**	
Gender (adolescents)							0.764
Male	384	47.7	204	47.0	180	48.5	
Female	415	51.5	226	52.1	189	51.0	
Others	6	0.8	4	0.9	2	0.5	
Age - baseline (adolescents) – (Mean ± SD)	805	12.6 ± 1.2	434	12.6 ± 1.3	371	12.6 ± 1.2	0.890
Age – 24 month follow-up (adolescents) – (Mean ± SD)	586	13.7 ± 1.5	305	13.7 ± 1.5	281	13.8 ± 1.4	0.266
Gender (caregivers)							0.585
Male	63	7.8	33	7.6	30	8.1	
Female	739	91.8	400	92.2	339	91.4	
Others	3	0.4	1	0.2	2	0.5	
Age - baseline (caregivers) – (Mean ± SD)	805	39.5 ± 8.1	434	39.1 ± 8.0	371	39.8 ± 8.3	0.228
Age – 24month follow-up (caregivers) – (Mean ± SD)	586	41.2 ± 7.6	305	41.2 ± 7.6	281	41.2 ± 7.7	0.973
Socioeconomic class							0.001
A	7	0.9	3	0.7	4	1.1	
B	31	3.9	8	1.8	23	6.2	
C	175	21.7	83	19.1	92	24.8	
D/E	592	73.5	340	78.4	252	67.9	

*chi-square test for categorical variables and a t-test for continuous variables

SD = standard deviation

necessitating adjustments for socioeconomic status in all analyses.

Table 2 presents descriptive data collected in the baseline and 12 and 24 months after regarding the variables related to family outcomes according to randomization groups. A statistically significant difference between groups was identified at baseline for family violence variables. A diff-in-diff approach was applied in multilevel models to address this discrepancy, accounting for baseline differences between the control and intervention groups. In terms of descriptive changes in prevalence over time among groups, it is noteworthy that the neglectful parenting style remains relatively stable in the control group (25%, 25%, and 26%, baseline, 12 and 24-month follow-up respectively) and shows a decreasing trend in the intervention group (33%, 27%, and 28%, baseline, 12 and 24-month follow-up relatively). Table 2 also outlines the distribution of variables related to parental substance use according to the group at baseline and follow-up. Caregivers' binge drinking increased significantly in the control group (from 12.7 to 22.6%) compared to a decrease in the intervention group (from 17.2 to 12.5%).

Table 3 shows data on adolescents' risk perception and lifetime drug use at baseline, 12 months, and 24 months. No significant differences were observed between groups

Table 2 Distribution of family outcomes and substance use among caregivers at baseline, 12, and 24 months

	Baseline			12 month follow-up			24 month follow-up		
	Control	Intervention	*p*-value*	Control	Intervention		Control	Intervention	
	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	*p*-value	Mean ± SD	Mean ± SD	*p*-value
Family violence									
Non-violent discipline	3.3 ± 1.6	3.1 ± 1.6	0.038	3.6 ± 0.1	3.4 ± 0.1	0.062	3.7 ± 1.4	3.6 ± 1.5	0.315
Verbal discipline	7.4 ± 1.1	7.3 ± 1.4	0.044	7.5 ± 1.1	7.6 ± 0.9	0.403	7.7 ± 0.9	7.7 ± 0.8	0.794
Physical discipline	17.4 ± 1.5	17.1 ± 2.4	0.016	17.6 ± 1.1	17.6 ± 1.2	0.903	17.8 ± 0.8	17.6 ± 1.6	0.047
Total violence	25.5 ± 2.6	24.8 ± 3.7	0.004	26.0 ± 2.3	26.0 ± 2.2	0.958	26.4 ± 1.8	26.3 ± 2.6	0.481
	N(%)	N(%)	p-value	N(%)	N(%)	p-value	N(%)	N(%)	p-value
Parenting style			0.063			0.555			0.966
Authoritative	169 (41.4)	121 (34.7)		152 (44.7)	130 (44.1)		140 (46.1)	128 (45.9)	
Authoritarian	71 (17.4)	53 (15.2)		57 (16.8)	54 (18.3)		56 (18.4)	49 (17.6)	
Indulgent	65 (15.9)	58 (16.6)		46 (13.5)	30 (10.1)		28 (9.2)	24 (8.5)	
Negligent	103 (25.3)	117 (33.5)		85 (25.0)	81 (27.5)		80 (26.3)	78 (28.0)	
Frequency of alcohol consumption (caregivers)			0.321			0.768			0.989
Never	330 (76.6)	275 (74.5)		258 (75.9)	231 (78.3)		244(80.0)	224 (79.7)	
Monthly or less	53 (12.3)	60 (16.3)		54 (15.9)	39 (13.2)		35 (11.5)	34 (12.1)	
2 to 4 times a months	40 (9.3)	28 (7.6)		22 (6.5)	20 (6.8)		22 (7.2)	20 (7.1)	
2 to 3 times a week	4 (0.9)	5 (1.4)		5 (1.5)	5 (1.7)		4 (1.3)	3 (1.1)	
4 or more times a week	4 (0.9)	1 (0.2)		1 (0.2)	0 (0.0)		0 (0.0)	0 (0.0)	
Binge drinking (caregivers)									
	55 (12.7)	61 (16.5)	0.124	62 (22.6)	46 (18.5)	0.250	45 (17.2)	29 (12.5)	0.136
Child's exposure to caregivers' drug use									
Social drinking			0.086			0.195			0.439
Never	325 (75.4)	270 (73.6)		261 (76.8)	217 (73.6)	0.195	243 (79.7)	226 (80.5)	
Sometimes	82 (19.0)	86 (23.4)		59 (17.4)	66 (22.4)		50 (16.4)	49 (17.4)	
Always	24 (5.6)	11 (3.0)		20 (5.8)	12 (4.0)		12 (3.9)	6 (2.1)	
Get drunk			0.002			0.289			0.956
Never	410 (95.4)	332 (91.2)		320 (94.1)	271 (91.9)		286 (93.8)	265 (94.3)	
Sometimes	14 (3.3)	31 (8.5)		17 (5.0)	17 (5.8)		18 (5.9)	15 (5.3)	
Always	6 (1.3)	1 (0.3)		3 (0.9)	7 (2.3)		1 (0.3)	1 (0.4)	
Smoke			0.684			0.505			0.800
Never	386 (90.0)	322 (89.0)		307 (90.3)	258 (87.5)		281 (92.1)	255 (90.8)	
Sometimes	26 (6.1)	21 (5.8)		18 (5.3)	19 (6.4)		13 (4.3)	13 (4.6)	
Always	17 (3.9)	19 (5.2)		15 (4.4)	18 (6.1)		11 (3.6)	13 (4.6)	

n.e. not estimable. Coefficients marked as 'not estimable' indicate that the model was unable to provide reliable estimates for certain variables due to issues such as insufficient data, high multicollinearity, or lack of variability in the data

***** p-value = We conducted a chi-square test for categorical variables and a t-test for continuous variables

SD = standard deviation

Table 3 Distribution of family outcomes and substance use among adolescents at baseline, 12, and 24 months

	Baseline			12-month follow-up			24-month follow-up		
	Control	Intervention	p-value	Control	Intervention		Control	Intervention	
	N(%)	N(%)		N(%)	N(%)	p-value	N(%)	N(%)	p-value
Initiation to drug use									
Alcohol	56 (13.1)	50 (13.5)	0.857	85 (25.0)	72 (24.4)	0.863	93(30.5)	86 (30,6)	0.976
Binge drinking	17 (4.0)	15 (4.12)	0.948	30 (8.8)	19 (6.4)	0.262	28 (9.2)	32 (11.4)	0.379
Tobacco	13 (3.0)	6 (1.62)	0.189	21 (6.2)	9 (3.1)	0.064	21 (6.9)	14 (5.0)	0.331
Inhalants	33 (7.8)	27 (7.3)	0.812	28 (8.2)	26 (8.8)	0.794	3 (1.0)	7 (2.5)	0.159
Risk perception of drug use									
Alcohol			0.293						
No risk	29 (6.8)	32 (8.7)		17 (4.9)	20 (6.8)	0.376	11 (3.6)	14 (5.0)	0.268
Light risk	41 (9.7)	46 (12.5)		25 (7.4)	29 (9.8)		22 (7.2)	32 (11.4)	
Moderate risk	117 (27.5)	86 (23.4)		69 (20.3)	65 (22.0)		72 (23.6)	63 (22.4)	
High risk	238 (56.0)	203 (55.4)		229 (67.4)	181 (61.4)		200 (65.6)	172 (61.2)	
Tobacco			0.689						
No risk	28 (6.6)	25 (6.8)		18(5.3)	19 (6.4)	0.199	9 (3.0)	9 (3.2)	0.171
Light risk	31 (7.3)	34 (9.2)		13 (3.8)	20 (6.8)		17 (5.6)	25 (8.9)	
Moderate risk	101 (23.7)	82 (25.0)		60 (17.7)	60 (20.3)		55 (18.0)	63 (22.4)	
High risk	266 (62.4)	217 (59.0)		249 (73.2)	196 (66.5)		224 (73.4)	184 (65.5)	
Marihuana			0.775						
No risk	25 (5.9)	24 (6.5)		18 (5.3)	20 (6.8)	0.141	11 (3.6)	14 (5.0)	0.136
Light risk	19 (4.5)	22 (6.0)		13 (3.8)	15 (5.1)		17 (5.6)	14 (5.0)	
Moderate risk	57 (13.4)	49 (13.3)		34 (10.0)	44 (14.9)		29 (9.5)	43 (15.3)	
High risk	324 (76.2)	273 (74.2)		275 (80.9)	216 (73.2)		248 (81.3)	270 (74.7)	

*p-value = We conducted a chi-square test for categorical variables and a t-test for continuous variables

at both follow-ups. As expected, lifetime drug use among adolescents increased over time in both groups.

Table 4 highlights improvements in parental and socio-emotional skills. The ability of parents to set clear rules about drug use improved more in the intervention group (mean score increased from 10.07 to 11.01) compared to the control group (mean score increased from 10.34 to 10.79). Adolescents' stress management skills also showed greater improvement in the intervention group (mean score increased from 6.84 to 7.89) compared to the control group (mean score increased from 6.93 to 7.50).

Table 5 presents the adjusted multilevel linear and logistic models that evaluated the program's effects on adolescent and family outcomes. No effect of the program was observed on the perception of risk or lifetime drug use among adolescents. However, the program significantly reduced negligent parenting (aOR 0.46, 95% CI 0.22;0.97) and parental binge drinking (aOR 0.24, 95% CI 0.08;0.74) after 24 months. Families in the intervention group were 54% less likely to report negligent behaviors, and caregivers were 76% less likely to engage in binge drinking compared to the control group after 24 months. Caregivers who participated in the program increased their ability to set clear rules regarding their adolescent's drug use compared to those in the control group after 24 months of follow-up (β 0.43, 95%CI 0.03; 0.83). Adolescents who participated in the program increased their ability to resolve family conflicts (β 0.79, 95%CI 0.11; 1.46) and their stress management skills (β 0.65, 95%CI 0.16; 1.15) compared to those in the control group after 24 months of follow-up.

Attrition

The attrition analysis showed no statistically significant differences in most sociodemographic variables and outcomes measured at baseline between students lost at the 12- and 24-month follow-up and those who responded. However, students lost at both follow-ups were slightly younger (mean age 12.4 years) than those who responded (mean age 12.7 years). Students lost at the 12-month follow-up were from lower SES and had a higher prevalence of inhalant use (12.2–6.4%). Families lost at 24-month follow-up were less authoritarian (31–41%) and practiced less non-violent discipline (mean 3.0–3.3) than those who followed (Table S1).

Ancillary analyses

We conducted ancillary analyses, including unadjusted and complete case analyses, to provide additional insights into the program's effects. In the unadjusted analysis (Table S2), the program demonstrated a reduction in parental binge drinking at 12 (OR 0.39, 95%CI 0.15; 0.99) and 24 (OR 0.28, 95%CI 0.09; 0.78) month follow-ups along with improvements in parental rules and expectations about drug use (β 0.37, 95%CI 0.02; 0.72), and adolescents' stress management skills (β 0.47,

Table 4 Distribution of adolescents' and parental skills at Baseline, 12, and 24 months

	Baseline			12-month follow-up			24 month follow-up		
	Control	Intervention		Control	Intervention		Control	Intervention	
	Mean (SD)	Mean (SD)	p-value	Mean (SD)	Mean (SD)	p-value	Mean (SD)	Mean (SD)	p-value
Parental skills									
Rules and expectations about drug use	10.86(2.10)	10.45(2.17)	0.006	10.83(2.02)	10.77(2.04)	0.682	10.98(1.88)	10.92(1.91)	0.676
Parental monitoring	14.17(2.53)	14.21(2.27)	0.839	13.76(2.65)	14.13(2.26)	0.065	14.02(2.49)	14.24(2.29)	0.270
Parental expectations	20.70(3.92)	21.02(3.43)	0.228	20.51(4.20)	20.66(3.95)	0.645	20.26(4.37)	20.59(3.97)	0.343
Quality of parent-child relationship	9.43(2.63)	9.26(2.54)	0.348	8.89(3.10)	9.2(2.79)	0.191	9.05 (3.04)	9.19(2.73)	0.570
Family problem-solving skills	21.52(5.29)	21.60(5.29)	0.834	20.38(7.11)	21.52(5.87)	0.029	21.44(6.47)	21.77(5.71)	0.515
Positive parental practices	21.45(3.99)	21.56(3.36)	0.686	20.07(5.07)	20.51(4.17)	0.240	20.87(4.13)	20.77(3.82)	0.771
Goal communication	7.07(1.61)	7.01 (1.59)	0.637	6.79(1.88)	6.90(1.54)	0.397	7.14 (1.51)	7.08(1.51)	0.634
Adolescents socioemotional skills									
Parental expectations	12.58(3.50)	12.00(3.46)	0.019	13.41(3.00)	13.13(3.11)	0.243	13.23(3.07)	12.80(3.24)	0.101
Quality of parent-child relationship	12.64(3.45)	12.41(3.35)	0.337	13.16(3.18)	12.67(3.14)	0.052	13.29(3.14)	13.05(3.11)	0.364
Family problem-solving skills	10.34(3.59)	10.07(3.41)	0.267	10.94(3.50)	10.70(3.68)	0.395	10.79(3.51)	11.01(3.48)	0.453
Stress management skills	6.93(2.39)	6.84(2.15)	0.586	7.54(2.39)	7.33(2.32)	0.259	7.50(2.16)	7.89 (2.40)	0.038
Family communications skills	12.50(3.30)	12.10(3.24)	0.080	13.01(3.02)	12.65(3.08)	0.137	12.94(2.93)	12.64(3.10)	0.228
Rules and expectations about drug use	5.87(2.14)	5.69 (2.12)	0.235	6.52(1.75)	6.44(1.71)	0.563	6.62(1.78)	6.40(1.82)	0.145
Peer pressure skills	13.15(3.47)	13.34(3.29)	0.435	14.50(2.78)	14.19(3.01)	0.177	14.34(2.94)	14.30(3.28)	0.870
Future orientation	16.92(3.17)	16.65(3.13)	0.228	18.17(2.22)	17.66(2.34)	0.005	18.26(2.34)	17.67(2.62)	0.004

*p-value = t-test for continuous variables

SD = standard deviation

95%CI 0.01; 0.93) at the 24-month follow-up. All effects found in the adjusted analysis were also observed in the unadjusted analysis, except for the family problem-solving skills of adolescents. However, without adjusting for sociodemographic variables, the program also showed an increase in verbal discipline (β 0.21, 95%CI 0.00; 0.41) and total violence (β 0.37, 95%CI 0.02; 0.72) after 12 and 24 months of follow-up, as well as an increase in physical discipline (β 0.56, 95%CI 0.03; 1.08) at the 12-month follow-up. This finding was not maintained in the adjusted model, suggesting the importance of the adjustment for confounders.

In the complete case analysis (Table S3), the protective effect of the program on parental binge drinking at the 24-month follow-up (OR 0.27, 95% CI 0.09, 0.86) was consistent with the ITT analysis. Improvements in parental skills related to rules and expectations about drug use (β 0.45, 95% CI 0.03, 0.86) and in adolescents' socioemotional skills, specifically in family problem-solving (β 0.80, 95% CI 0.19, 1.58) and stress management (β 0.61, 95% CI 0.09, 1.14), were also maintained from the ITT analysis.

Discussion

This study evaluated the long-term effect of the FF-BR 10–14 program in a sample of adolescents with a mean age of 12 years and one of their parents/caregivers, mostly from low-SES attending SARCs. No effect of the program was observed on the initiation of drug use among adolescents after 12- and 24-months of follow-up. Among caregivers who participated in the FF-BR 10–14 program, we observed a reduction in the prevalence of a negligent parental style and excessive alcohol consumption (binge drinking), as well as an increase in the ability to set clear rules regarding their children's drug use. Adolescents who participated in the program showed improvements in their ability to resolve family conflicts and manage their stress. Remarkably, this study holds significance as the only investigation in Latin America that

Table 5 Adjusted GLMM* multilevel models of the Famílias Fortes program's impact on adolescents and parents outcomes

	Generalized linear mixed models - program effect					
	12-month follow-up			**24-month follow-up**		
	aOR*	**95%CI**	***p*-value**	**aOR***	**95%CI**	***p*-value**
Parenting style						
Authoritative	ref			ref		
Authoritarian	1.34	0.65;2.75	0.429	1.02	0.48;2.17	0.953
Indulgent	0.53	0.25;1.11	0.091	0.61	0.25;1.48	0.272
Negligent	0.67	0.34;1.33	0.249	**0.46**	**0.22;0.97**	**0.041**
Initiation to drug use						
Alcohol	0.86	0.22; 3.51	0.841	1,26	0.06; 28.74	0.885
Binge drinking	0.54	0.08; 3.85	0.541	1.77	0.21; 15.03	0.602
Tobacco	1.02	0.18,5.74	0.981	1.53	0.15;15.58	0.718
Inhalants	1.31	0.48;3.56	0.592	4.6	0.24;86.62;	0.308
Risk perception of drug use						
Alcohol	0.83	0.53;1.32	0.448	0.90	0.57;1.44	0.670
Tobacco	0.79	0.49;1.28	0.346	0.82	0.50;1.34	0.421
Marihuana	0.70	0.41;1.20	0.190	0.80	0.46;1.40	0.441
Frequency of alcohol consumption (caregivers)						
Never						
Monthly or less	0.74	0.38; 1.46	0.388	0.88	0.42; 1.86	0.744
2 to 4 times a month						
2 to 3 times a week						
4 or more times a week						
Binge drinking (caregivers)	**0.41**	**0.15; 1.07**	**0.067**	**0.24**	**0.08; 0.74**	**0.013**
Child's exposure to caregivers' drug use						
Social drinking	1.23	0.62;2.44	0.549	0.88	0.41;1.91	0.750
Get drunk	1.29	0.39;4.22	0.677	0.67	0.19;2.41	0.540
Smoke	1.15	0.38;3.49	0.805	1.02	0.30;3.53	0.971
	12 months follow up			**24 months follow up**		
				β**	**95%CI**	**p-value**
Family violence						
Non-violent discipline	-0.20	-0.29;0.24	0.858	0.19	-0.09;0.48	0.183
Verbal discipline	0.13	-0.06; 0.31	0.169	0.18	-0.02;0.37	0.083
Physical discipline	0.20	-0.08;0.48	0.162	0.01	-0.29;0.31	0.924
Total violence	0.42	-0.05;0.89	0.077	0.47	-0.03;0.97	0.063
Parental Skills						
Rules and expectations about drug use	0.34	-0.22; 0.91	0.234	**0.43**	**0.03; 0.83**	**0.033**
Parental monitoring	0.19	-0.61; 0.98	0.646	0.07	-0.54; 0.68	0.820
Parental expectations	-0.29	-1.38; 0.81	0.605	0.05	-1.25; 1.36	0.933
Quality of parent-child relationship	0.31	-0.66; 1.28	0.527	0.09	-0.94; 1.11	0.868
Family problem-solving skills	0.86	-1.45; 3.19	0.465	0.21	-2.06; 2.48	0.856
Positive parental practices	0.31	-1.60; 1.43	0.753	-0.08	-1.60; 1.43	0.912
Goal communication	0.20	-0.30; 0.70	0.434	0.07	-0.30; 0.44	0.721
Adolescent's Socioemotional skills						
Parental expectations	0.25	-0.53; 1.04	0.526	0.32	-0.48; 1.13	0.430
Quality of parent-child relationship	-0.31	-1.14; 0.52	0.461	0.12	-0.55; 0.80	0.720
Family problem-solving skills	0.09	-0.54; 0.72	0.787	**0.79**	**0.11; 1.46**	**0.022**
Stress management skills	-0.06	-0.05; 0.40	0.794	**0.65**	**0.16; 1.15**	**0.009**
Family communications skills	-0.08	-0.66; 0.49	0.773	0.22	−0.039; 0.83	0.482
Rules and expectations about drug use	0.04	-0.28; 0.37	0.800	0.06	-0.28; 0.42	0.714

Table 5 (continued)

	12 months follow up			24 months follow up		
				β**	95%CI	p-value
Peer pressure skills	-0.26	-0.91; 0.40	0.443	0.05	-0.64; 0.75	0.876
Future Orientation	-0.03	-0.54; 0.48	0.909	-0.09	-0.64; 0.46	0.746

*aOR = adjusted odds ratio for categorical outcomes. Adjusted for adolescents and caregivers age, sex and socioeconomic status

**β model coefficient for continuous outcomes

GLMM: Generalized Linear Mixed Models

evaluated SFP through RCTs and is considered a gold standard study design for intervention evaluation [36].

Over 24 months, the program had no significant effect on drug use among Brazilian adolescents. This contrasts with North American studies indicating long-term effects, suggesting a long-lasting reduction or delay in the onset of adolescent drug use, even after 5–6 years [7–9]. In contrast, our findings align with some European and Latino-American studies that also reported no effect of the program on reducing adolescents' substance use, including Colombia (12- and 18-month post-intervention) [37], Chile (6-month) [12], Sweden (12-, 24- and 36-month) [11], Germany (6- and 18-month) [38], Polland (12- and 24-month) [13] and the UK (24-month) [14]. Several factors may have contributed to these null results, including potential challenges with the cultural adaptation of the program, the younger age of the adolescents participating in the program, and possible inadequacies in lessons specifically addressing drug use prevention.

A global review of the SFP adaptation process showed variations in effectiveness, hinting at a potential incompatibility between cultural adaptation and target audience needs [39]. In Brazil, studies assessing the need for cultural adaptations of the FF-BR 10–14 program emphasized the requirement for further adjustments in methods and activities. These included making video materials more attractive and understandable to the Brazilian population and aligning intervention materials with the socioeconomic reality and educational levels of participants [15, 39]. However, it seems that the adjustments made were more surface adaptations, which refer to the program's superficial aspects, such as language, presentation format, or visual materials [40]. A process evaluation conducted in parallel with the RCT suggested that challenges persisted with the current version of the FF-BR 10–14, including issues with content alignment, low literacy among caregivers, implementation logistics, low fidelity, and limited engagement of adolescents with the proposed activities [41]. Despite translation and surface adaptation efforts, the current Brazilian version of the SFP may not fully fit the local context, warranting a re-evaluation of the potential impacts on effectiveness.

While our study demonstrated positive effects on mediating factors such as parenting practices and adolescent coping skills, the absence of significant changes in adolescent substance use suggests that the intervention dosage may have been insufficient. Research indicates that more intensive programs often yield greater improvements in behavioral outcomes [42] particularly in adolescents, who may require more sustained engagement to alter established patterns of behavior. Therefore, we propose that future iterations of the program explore increasing the number of intervention sessions or enhancing session intensity.

Furthermore, activities designed for adolescents may not be optimally effective in reducing substance consumption, considering the wide age range targeted (10–14 years old). Activities tailored for younger adolescents may not resonate with older adolescents, potentially compromising the effectiveness of these lessons [5].

The nested process evaluation within the RCT identified low adolescent engagement in program activities (internal reports). This is unsurprising considering the program's 1980s origins, which may not resonate with the interests of Generation Z adolescents. While parental needs for communication and monitoring skills training may have remained consistent across generations, the current generation of adolescents undoubtedly differs significantly from their counterparts decades ago.

In the short-term evaluation, FF-BR 10–14 initially effectively reduced parental negligence at the 6-month follow-up [17], and this effect was sustained for at least 24 months. This finding aligns with studies from Colombia and the US, which reported sustained improvements in family cohesion and supervision and reduced aggressive behavior 12 months after the baseline assessment [10, 37, 43]. It is well established in the literature that adolescents are less likely to engage in risky behaviors, such as drug consumption when parents are actively involved in their children's lives. Studies have consistently shown that parental involvement and monitoring are significant protective factors against adolescent substance use [44].

The program significantly enhanced parents' ability to establish clear rules against drug use for their children after the 24-month follow-up. Research on drug prevention consistently indicates that precise and firm parental rules are a critical protective factor against the initiation and progression of drug use among youth [45].

These clear rules create well-defined boundaries, helping adolescents understand family and social expectations regarding substance use and reinforcing behavior norms that discourage it [46]. In light of current literature, the program's effects on reducing parental negligence and strengthening rule-setting practices may substantially contribute to preventing substance use. Future studies should examine whether these positive changes in parental behaviors and reduced negligence effectively prevent adolescent drug use through a mediation model.

The program also reduced binge drinking among parents, an important outcome given the well-established literature on the relationship between heavy parental alcohol consumption and children's drinking behavior [47–49]. Heavy parental drinking is a pivotal factor in predicting the initiation and progression of alcohol consumption in offspring [47, 49]. Furthermore, reducing binge drinking among caregivers also had a significant individual effect; that is, the program appeared to work as a preventive intervention for the adults who received it. In addition to mitigating chronic diseases, reducing parental binge drinking positively influences cognitive function [50], diminishes intimate partner violence [51], reduces traffic accidents [52–54], enhances workplace productivity [55], and alleviates the burden on public authorities and health services [56]. Further studies are warranted to understand this unexpected effect and assess whether a reduction in excessive parental alcohol consumption influences adolescent alcohol use, as suggested by existing literature.

Regarding adolescents' socioemotional skills, we also found an increase in their ability to resolve family conflicts and manage their stress compared to those in the control group. The socioemotional skills enhanced by the Famílias Fortes program are highlighted in the literature as playing a significant role in drug prevention among adolescents [57]. The ability to effectively resolve conflicts tends to reduce tensions in the family environment, improving communication and relationships among its members. Additionally, it enables young people to negotiate differences within the family without resorting to substances to escape or cope [58]. Furthermore, improved stress management equips adolescents with healthy strategies to deal with everyday pressures [59]. These improvements in socioemotional skills have intermediate implications for drug prevention, as adolescents with these competencies are better equipped to resist social and emotional pressures that may lead to substance use. Therefore, by strengthening these socioemotional skills, the Famílias Fortes program promotes the overall development of adolescents and potentially acts in drug prevention by offering them resilient alternatives to face life's challenges [60].

Limitations

This study had some limitations, notably, a 21.6% attrition rate during the 12-month follow-up and a 27.2% at 24-month follow-up. However, it is important to contextualize this as a relatively low attrition rate compared to other Brazilian studies where sample losses exceeded 30% [61]. Another limitation was self-reported scales, which may have generated information bias. Nevertheless, most SFP studies have opted for self-completed questionnaires because of their lower cost and reduced need for rater training [61].

Conclusion

The results of this study indicate that the FF-BR 10–14 did not significantly reduced adolescent substance use after 12 and 24 months of follow-up. However, positive long-term effects were observed in the logic model mediators, such as a reduction in negligent parenting and parental binge drinking, and improvements in adolescents' conflict resolution and stress management skills. These findings highlight the program's role in enhancing the family environment and supporting prevention efforts through intermediary behaviors, with more substantial changes in parental conduct. Future studies should explore factors that are responsible for the lack of effect in preventing adolescent substance use.

Abbreviations

ABEP	Brazilian Association of Research Companies
CEBRID	Brazilian Center for Psychotropic Drugs Information
CONSORT	Consolidated Standards of Reporting Trials
GLMM	Generalized Linear Mixed Models
ITT	Intention-to-treat
MAR	Missing at Random
PCSQ	Parent/Caregiver Survey Questionnaire
FF-BR 10–14	Famílias Fortes Program
REBEC	Brazilian Ministry of Health Register of Clinical Trials
RTC	Randomized Controlled Trial
SARCs	Social Assistance Reference Centers
SES	Socioeconomic Status
SFP	Strengthening Families Program
SFP 10–14	Strengthening Families Program for children and adolescentes aged 10–14 years
UNODC	United Nations Office on Drugs and Crime
YPSQ	Youth Survey Questionnaire

Supplementary Information

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Supplementary Material 1

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Author contributions

Juliana Valente conducted the data analyses and drafted the first version of the manuscript. Patricia Galvão, Fabiane Gurbert, Lidiane N Rebouças, and Luis Eduardo Soares-Santos collected the data and revised the manuscript. Sheila C Caetano revised the final version of the manuscript. Zila Sanchez acquired the

grant, conceptualized and designed the study, was responsible for the data collection and supervision, and revised and approved the final version of the manuscript. All authors approved the final version of the manuscript.

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Data availability
Data supporting this study will be made available upon reasonable request to the corresponding author.

Declarations

Ethics approval and consent to participate
The Research Ethics Committee approved the study protocol of the Federal University of São Paulo (number: 4.890.815). All procedures in the current study followed the institutional norms and ethical standards of the national research committee, and the 1964 Declaration of Helsinki and further amendments. Parents/guardians completed Informed Consent Forms and adolescents completed Informed Assent Forms stating that they agreed to participate in the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Author details
[1]Department of Preventive Medicine, Universidade Federal de São Paulo, Rua Botucatu, 740 - Vila Clementino, São Paulo, SP 04023-062, Brazil
[2]Department of Psychiatry, Universidade Federal de São Paulo, Rua Major Maragliano, 241 - Prédio Acadêmico, Vila Mariana, São Paulo, Brazil
[3]Department of Nursing, Universidade Federal do Ceará, Rua Alexandre Baraúna, 1115 - Rodolfo Teófilo, Fortaleza, CE 60430-160, Brazil
[4]Rua Botucatu 740, São Paulo, SP, Brazil

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