



One-year follow-up of Pre-exposure Prophylaxis (PrEP) users in Ceará, Brazil: adherence, behavioral patterns, and outcomes

Acompanhamento anual de usuários da Profilaxia Pré-Exposição (PrEP) no Ceará, Brasil: adesão, padrões comportamentais e resultados e desfechos

Seguimiento de un año de usuarios de Profilaxis Pre-Exposición (PrEP) en Ceará, Brasil: adherencia, patrones de comportamiento y resultados

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ABSTRACT

Background and Objectives: Pre-exposure prophylaxis (PrEP) is a highly effective strategy for preventing HIV, especially among sexual and gender minorities. This study evaluated adherence, behavioral patterns, and health outcomes among individuals (including gay and bisexual men, other men who have sex with men (MSM), and transgender women) using Pre-Exposure Prophylaxis (PrEP) in Ceará, Brazil over the course of one year. **Methods:** A retrospective cohort design was used to analyze secondary data from the Logistic Control System of Medicines. The study included 192 participants: heterosexual (50), homosexual (125), bisexual (17), and other men who have sex with men and one transgender woman (n=192), who initiated PrEP between December 2017 and June 2021. **Results:** The findings indicated a high adherence rate, with a mean rate of 2.24 missed pills per month, and no new HIV infection was reported among participants. However, 16 cases of syphilis were detected, highlighting a discrepancy between self-reported condom use and actual sexual behavior. Additionally, no significant association was found between educational level and condom use, suggesting that higher education does not necessarily lead to safer sexual practices. Some participants (45) reported experiencing adverse drug reactions, with nausea being the most common symptom. **Conclusion:** The study showed high adherence to PrEP and an absence of new HIV infections. However, the discrepancy between self-reported condom use and actual behavior indicates a need for combined strategies to address risk compensation and to improve monitoring of the population using PrEP.

Keywords: Pre-Exposure Prophylaxis (PrEP). Prevention. Sexual and Gender Minorities. Sexual Behavior. Treatment Outcome.

RESUMO

Justificativa e Objetivos: A profilaxia de pré-exposição (PrEP) é uma estratégia altamente eficaz para prevenção do HIV, especialmente entre minorias sexuais e de gênero. Este estudo avaliou a adesão, os padrões comportamentais e os desfechos de saúde entre indivíduos (incluindo homens gays e bissexuais, outros homens que fazem sexo com homens [HSH] e mulheres transgênero) que usaram a PrEP no Ceará, Brasil, durante um ano. **Métodos:** Foi usado um delineamento de coorte retrospectiva para analisar os dados secundários do Sistema de Controle Logístico de Medicamentos. O estudo incluiu 192 participantes: heterossexuais (50), homossexuais (125), bissexuais (17) e outros homens que fazem sexo com homens, e uma mulher transgênero (n=192), que iniciaram a PrEP entre dezembro de 2017 e junho de 2021. **Resultados:** Os achados indicaram uma alta taxa de adesão, com uma taxa média de 2,24 comprimidos não tomados por mês, e novas infecções por HIV não foram relatadas entre os participantes. Porém, foram detectados 16 casos de sífilis, evidenciando uma discrepância entre o uso de preservativo autorrelatado e o comportamento sexual real. Além disso, não foi encontrada uma associação significativa entre nível de escolaridade e uso de preservativo, sugerindo que um maior nível de instrução não leva necessariamente a práticas sexuais mais seguras. Alguns participantes (45) relataram reações adversas ao medicamento, sendo a náusea o sintoma mais comum. **Conclusão:** O estudo mostrou uma alta adesão à PrEP e ausência de novas infecções por HIV. Porém, a discrepância entre o uso de preservativo autorrelatado e o comportamento real indica a necessidade de estratégias combinadas para avaliar a compensação de risco e melhorar o monitoramento da população que usa a PrEP.

Descritores: Profilaxia Pré-Exposição (PrEP). Prevenção. Minorias Sexuais e de Gênero. Comportamento Sexual. Desfecho do Tratamento.

RESUMEN

Justificación y Objetivos: La profilaxis preexposición (PrEP) es una estrategia altamente eficaz para la prevención del VIH, especialmente entre las minorías sexuales y de género. Este estudio evaluó la adherencia, los patrones de comportamiento y los resultados de salud en personas (incluidos hombres gays y bissexuales, otros hombres que tienen sexo con hombres [HSH] y mujeres transgénero) que utilizaron PrEP en Ceará, Brasil, durante un año. **Métodos:** Se utilizó un diseño de cohorte retrospectivo para analizar datos secundarios del Sistema de Control Logístico de Medicamentos. El estudio incluyó a 192 participantes: heterossexuales (50), homossexuales (125), bissexuales (17) y otros hombres que tienen sexo con hombres y una mujer transgénero (n=192), que iniciaron la PrEP entre diciembre de 2017 y junio de 2021. **Resultados:** Los hallazgos indicaron una alta tasa de adherencia, con un promedio de 2,24 píldoras omitidas al mes, y no se reportaron nuevas infecciones por VIH entre los participantes. Sin embargo, se detectaron 16 casos de sífilis, lo que evidencia una discrepancia entre el uso de preservativo autoinformado y el comportamiento sexual real. Además, no se encontró una asociación significativa entre el nivel educativo y el uso del preservativo, lo que sugiere que un mayor nivel educativo no necesariamente conlleva prácticas sexuales más seguras. Algunos participantes (45) reportaron reacciones adversas al medicamento, siendo las náuseas el síntoma más común. **Conclusión:** El estudio mostró una alta adherencia a la PrEP y la ausencia de nuevas infecciones por VIH. Sin embargo, la discrepancia entre el uso de preservativos autoinformado y el comportamiento real indica la necesidad de estrategias combinadas para evaluar la compensación del riesgo y mejorar el seguimiento de la población que utiliza PrEP.

Palabras Clave: Profilaxis Pre-Exposición (PrEP). Prevención. Minorías Sexuales y de Gênero. Comportamiento Sexual. Resultado del Tratamiento.

INTRODUCTION

Pre-exposure prophylaxis (PrEP) has been recognized as a fundamental strategy in addressing the HIV epidemic within the framework of combination prevention. This approach integrates various (biomedical, behavioral, and socio-structural) prevention modalities tailored to the specific needs and contexts of individual users.¹ Globally, HIV remains a major public health issue, with millions of new infections occurring annually despite advances in prevention and treatment. In Brazil, the epidemic continues to strongly affect key populations, including gay, bisexual, and other men who have sex with men (GBM), as well as transgender women. In the State of Ceará, a total of 17,582 HIV cases were reported from 2014 to October 2023, with new cases among adults in 2022 (1,712) and 2023 (1,139).² Notably, the Unified Health System (SUS) in Brazil provides free access to oral PrEP, specifically tenofovir/emtricitabin (TDF/FTC) 300 e 200 mg, for (GBM) and transgender women since December 2017.^{3,4}

Following the incorporation of PrEP into the SUS and the drug's registration in Brazil, the Ministry of Health (MS) began its implementation in 36 selected facilities in the States of Amazonas, Bahia, Brasília, Ceará, Minas Gerais, Rio de Janeiro, Rio Grande do Sul, Santa Catarina, São Paulo, Paraná, and Pernambuco. These states were chosen based on their epidemiological profiles, particularly their higher prevalence of HIV infection, as well as the organizational capacity of their HIV/Aids care services. The selection criteria for these units included: (i) strong interest in adopting the new prevention method, (ii) presence of an Antiretroviral Drug Dispensing Unit (UDM), (iii) consistent use of the Logistic Control System of Medicines (SICLOM), (iv) availability of outpatient care for individuals exposed to HIV through sexual violence, unprotected sexual activity, or occupational and non-occupational accidents, and (v) provision of Post-Exposure Prophylaxis for HIV (PEP).¹

Concerns persist regarding risk compensation (reduced condom use or increased sexual partnerships leading to higher sexually transmitted infection (STI) rates), as PrEP protects only against HIV.⁵ This study aimed to characterize adherence, sexual behaviors, and health outcomes among PrEP users in Ceará, focusing on GBM and transgender women, to inform targeted HIV prevention strategies.⁴

During the initial implementation of PrEP, the potential for risk compensation (defined as an increase in sexual partnerships, decreased condom use, and a subsequent rise in STIs) was the primary concern, as PrEP's protective efficacy is limited to HIV prevention. However, recent data from the United Nations Program on HIV/Aids (UNAIDS) show that member countries

of the Global Coalition for HIV Prevention have achieved significant reductions in new HIV infections. Nonetheless, MSM continue to represent a critical population for behavioral research within the framework of combination prevention, and STI management. This study was significant for its potential to inform local and regional public health policies by identifying specific behavioral patterns and adherence challenges in Ceará. Therefore, this study aimed to guide the optimization of PrEP delivery and support services for these vulnerable populations.

METHODS

Study Design

This retrospective cohort study used a quantitative approach to characterize PrEP adherence, behavioral patterns, and outcomes among 192 individuals in Ceará, Brazil. Since all participants were PrEP users (without a non-exposed comparison group), the analysis was descriptive, and effect measures with 95% confidence intervals were not applicable.

Participants

The study population included individuals registered in the SICLOM program, which is managed by the Brazilian Ministry of Health. The inclusion criteria for participants were as follows: age ≥ 18 years; daily PrEP use (tenofovir, 300 mg/emtricitabine, 200 mg) between December 2017 and June 2021; and completion of at least three follow-up visits (30, 60, and 180 days post-initiation). The exclusion criteria were as follows: suspected HIV immunological window, inconclusive and/or confirmatory HIV tests, or current use of antiretroviral therapy. Only individuals who provided demographic data, details about their sexual behavior, adherence levels, and health outcomes (in addition to variables that included condom use, missed doses, reasons for non-adherence, adverse drug reactions (ADRs), and STI/HIV test results) were included in the study. In this context, the present study aimed to evaluate 192 individuals using PrEP in the State of Ceará, Brazil, over the course of one year.

Data Collection

Secondary data were obtained from SICLOM records at two specialized infectious disease services in Ceará (Hospital São José de Doenças Infecciosas and Policlínica Dr. Lusmar Veras Rodrigues), which were among the first in Brazil to implement PrEP. Data collection occurred from July to August 2022, after approval from the pharmaceutical assistance manager of the Ceará State Health Department (SES-CE), who granted access to SICLOM. All data accessed came from clinical monitoring forms, completed by health professionals during PrEP consultations.

Adherence levels were evaluated monthly through SICLOM records and participants' self-report of missed doses. High adherence was defined as 0-3 missed doses per month (which corresponds to near-perfect daily use). This level of adherence exceeds the minimum weekly thresholds recommended in the Brazilian

Ministry of Health's Clinical Protocol and Therapeutic Guidelines for Oral PrEP (≥4 doses/week for most populations). The analysis also considered the influence of social demographics, PrEP utilizations, and social behaviors (Table 1).⁶

Table 1. Characterization of selected variables and their representations.

Sociodemographic Aspects	
Variables	Metrics
Age	Calculated in years based on the birth date reported by PrEP users.
City of Residence	The city where PrEP users currently reside.
Sexual Orientation	Heterosexual, Homosexual, Gay, Lesbian, or Bisexual orientations of PrEP users.
Gender Identity	Male, Female, Transgender Woman, Transvestite or Transgender Woman, Transgender Man identities of PrEP users.
Race or Ethnicity	White, Black, Yellow (Asian), Brown, and Indigenous race or ethnicity reported by PrEP users.
Education Level	None or No Formal Education; 1-3, 4-7, 8-11, and 12 years, or more declared by PrEP users.
PrEP Utilization	
Medical Monitoring	Types of medical monitoring of PrEP users (Public or Private).
Reason for PrEP Choice	Reasons (Referral by a healthcare professional; awareness through print or internet campaigns, peer educators, friend communication, or guidance from NGOs) why individuals sought PrEP.
Frequency of PEP Use	Number of times PEP was used in the last 12 months prior to starting PrEP.
Sexual Behavior	
Frequency of Sexual Relations	Number of sexual intercourse events reported per period
Frequency of Condom Use	Number of times individuals used condoms in their sexual relationships in the 3 months prior to starting PrEP and again after 180 days of use.
Type of Unprotected Sexual Relation	Types of sexual relation individuals engaged in during the 6 months prior to starting PrEP and after 180 days of use: Insertive Anal (anal penetration), Receptive Anal (being penetrated anally), Insertive Vaginal (vaginal penetration), Receptive Vaginal (being penetrated vaginally), Not applicable.
Sexual Relation with HIV+ Partner	A dummy variable indicating whether PrEP users engaged in unprotected sexual relations with an HIV-positive partner in the past 6 months (yes, no, and I don't know).
Receipt of Remuneration for Sex	A dummy variable indicating whether individuals who opted for PrEP received remuneration for sex in the past 6 months (yes or no).

Abbreviations: PrEP - Pre-Exposure Prophylaxis for HIV; NGOs - Non-Governmental Organizations; PEP - Post-Exposure Prophylaxis for HIV; HIV - Human Immunodeficiency Virus; TDF/FTC - Tenofovir/Emtricitabine.

Data Analysis

Data were organized using Microsoft Excel® (2016) and analyzed with GraphPad Prism 8.0. Descriptive statistics (frequencies, means, and standard deviations) were used to summarize participant characteristics and outcomes. Chi-square tests were used to assess associations between categorical variables (e.g., condom use and educational level), with statistical significance (p < 0.05). Continuous variables were analyzed using either Student's *t*-test or the Mann-Whitney *U* test, depending on their distribution, to reject or not reject the null hypothesis.

Research Ethics

The study was conducted following the ethical standards (Resolutions 466/2012, 510/2016, and 580/2018) from the Brazilian Ministry of Health. It was approved by the local Research Ethics Committees (CAAE: 21210319.7.30001.5051). As secondary data were used, individual consent was not required; however, data were anonymized to protect participants' privacy.

RESULTS

A total of 192 participants were included in the study, with key demographic data presented, including sexual orientation. In this analysis, gender identities were not separated, focusing solely on sexual orientation (Table 2).

Table 2. Study Population Characteristics.

	No. (%)
Mean Age (± Standard Deviation)	33 ± 8.2
Gender identity	
Male cisgender	157
Female cisgender	34
Female transgender	1
Sexual Orientation	
Homosexual	125 (65.10)
Heterosexual	50 (26.0)
Bisexual	17 (8.9)
Race and/or Ethnicity	
Asian	1
White	65
Mixed Race	112
Black	13
Not Declared	1

The frequency of PrEP use among MSM was significantly higher compared to heterosexual individuals. A chi-square test indicated a statistically significant association ($p < 0.00001$) between PrEP use and MSM (Table 3).

Table 3. Sexual Orientation of Pre-exposure prophylaxis users.

Sexual Orientation	Gender Identity		Total
	Male (Cis or Trans)	Female (Cis or Trans)	
Bisexual	16 (8.3)	1 (0.5)	17 (8.9)
Heterosexual	17 (8.9)	33 (17.2)	50 (26.0)
Homosexual	124 (64.6)	1 (0.5)	125 (65.1)

Participants in the study chose to use PrEP based on personal choice. When asked about their reasons for choosing PrEP, nearly half (50%) cited influence from communication channels such as the internet, whereas 46% cited referrals from healthcare professionals. To evaluate engagement in unsafe sexual practices, all participants were asked about their condom use. Among the participants, 33 individuals had up to 12 years of schooling, whereas 51 reported having 12 or more years of education. One participant did not provide information about their educational level. An analysis was conducted to assess the number of participants who reported consistent condom use during sexual intercourse. The chi-square analysis showed no statistically significant difference between groups with varying educational levels concerning consistent condom use ($p = 0.34$).

Rapid test results indicated that 16 individuals tested positive for syphilis, of which 7 reported using condoms consistently. Testing for syphilis, HIV, and viral hepatitis was conducted using rapid immunochromatographic tests provided by the State Health Department (Ministry of Health), or via serological exams performed in accredited public laboratories.⁶ To analyze adherence to prophylaxis, responses to adherence-related variables were evaluated and statistical analyses were performed to identify patterns or significant factors influencing adherence. These variables included the number of unused pills, reasons for non-use, and reports of ADRs. Key findings

revealed a mean value of 2.24 missed pills per month (standard deviation: 5.12). Most people showed good adherence (0-3 missed doses per month), according to the classification set by the Brazilian Ministry of Health guidelines.⁶ The main reasons for missing doses are shown below (Table 4).

Table 4. Treatment adherence to pre-exposure prophylaxis (PrEP) and factors affecting adherence.

Reasons for forgetting PrEP	Quantity
It was not forgotten	93
It was forgotten, but the reason was not specified	56
Travel	22
Medication ran out	17
Adverse reaction	4

Categorization of reasons for non-adherence (missed doses) based on self-reported data from medical records: It was not forgotten (no missed doses reported or perfect daily use); It was forgotten but not specified; Travel-related issues; Medication supply ran out; Adverse reaction (self-reported ADRs).

In collecting data on treatment adherence, blood tests to assess pharmacokinetics were not performed, relying solely on patient self-reports. The correlation between drug and alcohol use and better or worse PrEP adherence did not yield significant results in our population ($p = 0.52$).

To estimate the prevalence of PrEP use and identify determinants of high adherence among transgender and cisgender men and women, significant differences in PrEP use and adherence by gender identity were observed. Participants who reported that their "medication ran out" were not referring to issues in accessing additional doses, as no medication shortages occurred during the study period.

At the end of the study’s follow-up period, 81 participants underwent repeat rapid HIV testing, and all results were non-reactive. Notably, five of them did not complete the HIV rapid test but were tested for hepatitis C (HCV), hepatitis B (HBV), and syphilis, and all results were also non-reactive. Regarding ADRs, 45 participants reported experiencing some form of change. When asked about specific symptoms, they reported diarrhea (8), flatulence (6), abdominal pain (2), nausea (15), and other symptoms (14). Two individuals discontinued PrEP due to ADRs. Participants who reported ADRs also underwent laboratory tests for transaminases, proteinuria, and creatinine clearance. The tests were performed in laboratories accredited by the public health network (Table 5).

Table 5. Clinical Laboratory Outcomes of people who reported adverse drug reactions.

Participants	Proteinuria	Liver Enzymes	Creatinine (ml/min)
26	Absent	Normal	>60 ml/min
51	Absent	Normal	>60 ml/min
165	Absent	Normal	>60 ml/min
105	Absent	Normal	>60 ml/min
124	Absent	Altered	>60 ml/min
126	Absent	Normal	>60 ml/min
157	Absent	Normal	>60 ml/min
183	Absent	Normal	>60 ml/min
2	Absent	Normal	>60 ml/min
90	Absent	Normal	>60 ml/min
68	Absent	Altered	>60 ml/min
110	Absent	Normal	>60 ml/min
147	Absent	Altered	>60 ml/min
156	Absent	Normal	>60 ml/min
159	Absent	Normal	>60 ml/min
164	Present	Normal	>60 ml/min
27	Absent	Normal	>60 ml/min
1	Not performed	Normal	>60 ml/min
4	Not performed	Normal	>60 ml/min
17	Not performed	Normal	>60 ml/min
97	Absent	Normal	>60 ml/min
54	Not performed	Not performed	>60 ml/min
52	Absent	Normal	>60 ml/min
92	Absent	Normal	>60 ml/min
102	Not performed	Not performed	>60 ml/min
127	Present	Absent	>60 ml/min
133	Absent	Normal	>60 ml/min
146	Absent	Altered	>60 ml/min
174	Absent	Normal	>60 ml/min
185	Present	Normal	>60 ml/min
188	Absent	Normal	>60 ml/min
9	Not performed	Normal	>60 ml/min
83	Absent	Normal	>60 ml/min
143	Absent	Normal	>60 ml/min
172	Absent	Normal	>60 ml/min
173	Absent	Normal	>60 ml/min
192	Absent	Not performed	>60 ml/min
74	Absent	Normal	>60 ml/min
71	Absent	Normal	>60 ml/min

57	Absent	Normal	>60 ml/min
129	Present	Normal	>60 ml/min
130	Present	Normal	>60 ml/min
136	Absent	Normal	>60 ml/min
163	Absent	Normal	>60 ml/min
177	Present	Normal	>60 ml/min

It is noteworthy that six individuals presented with proteinuria; however, their creatinine levels (a key marker of kidney injury) were within normal limits. Transaminase levels were elevated in two individuals, neither of whom discontinued PrEP due to ADRs.

DISCUSSION

The statistically significant association ($p < 0.00001$) between PrEP use and MSM underscores the importance of targeted intervention strategies for these populations, given the disproportionate burden of HIV they face.⁶ As shown above, the frequency of PrEP use was predominantly concentrated among MSM compared to heterosexual individuals, highlighting the distinct demographic profile of users in this context.

Healthcare professionals should adopt personalized approaches when discussing PrEP, considering the unique challenges MSM face (such as stigma and discrimination), which may discourage them from seeking preventive care.⁷ Additionally, the finding that nearly half (50%) of participants cited influence from communication channels like the internet (while 46% were referred by healthcare professionals) suggests that multiple avenues (both digital and professional) play a significant role in PrEP uptake.

It is well-established that higher levels of education are often linked to better access to information, improved decision-making, and reduced engagement in risk-related behaviors.⁸ However, contrary to this belief, the present study found no significant association between educational level and condom use. This challenges the idea that access to information alone drives behavior change, suggesting that in Ceará, structural factors (such as stigma, discrimination, or limited access to sexual health resources) may outweigh educational attainment. This finding indicates that stigma is a significant barrier to preventive care among vulnerable populations in Brazil. It highlights the need for culturally tailored interventions (such as peer-led outreach or community-based counseling) to address the specific social and psychological drivers of risky behavior among MSM and transgender women.³

The detection of 16 syphilis cases (with 7 of these individuals claiming consistent condom use) contradicts self-reported data on condom use. It highlights a discrepancy between perceived and actual practices, suggesting possible oral transmission, as condoms are seldom used for oral sex.⁹ This situation highlights the

need for caution when interpreting self-reported data in clinical settings.¹⁰ Although self-reporting is a convenient method for data collection, its limitations are evident, as individuals' perceived behaviors may not always match their actual practices. This is particularly relevant in health-related measures, in which observer-reported data may provide more accurate insights.¹¹

These findings emphasize the need for routine screening for STI (beyond HIV) as a core component of PrEP programs. It is also crucial to include behavioral interventions to correct misconceptions about the extent of PrEP's protection. In this regard, the Pre-Exposure Prophylaxis Expanded (PrePEX) Study (which included 4,275 participants) found a link between increased STI rates among gay and bisexual men using PrEP compared to data collected before PrEP was widely used.⁷ Conversely, a cross-sectional study of Latino MSM (aged 20-39 years) showed that PrEP use was positively associated with condom use, particularly among those with multiple sexual partners.¹²

A professional advised all participants who used PrEP that treatment adherence is essential for preventing HIV infection. Existing studies have shown that adherence to prophylaxis is a key factor in preventing HIV acquisition.¹³ However, since this study relied solely on patient self-reports (rather than blood tests to assess pharmacokinetics), both adherence and forgetfulness data should be used for qualitative analysis. This approach supports studies that highlight the need to assess PrEP adherence. Although PrEP substantially reduces the likelihood of HIV acquisition, low levels of adherence can reduce its protective benefits.¹⁴ The current findings highlight the significant role of problematic alcohol consumption and cocaine use on PrEP adherence (although this correlation did not yield statistically significant results within the evaluated population). Identifying and addressing these issues within PrEP delivery settings may enhance its effectiveness.¹⁴ Significant differences in PrEP use and adherence based on gender identity suggest that surveillance, outreach, and prescription practices should consider the unique risk factors associated with different gender identities.¹⁵ This article focuses primarily on economic factors, as the studied population does not live in a country with an equitable healthcare system, although free access to medication via SUS was available. However, adherence remains a challenge for individuals taking daily medication, as even free access does not ensure consistent daily use.¹⁶

The absence of reactive HIV tests among the 81 participants tested at the end of the follow-up period (along with the non-reactive results for HCV, HBV, and syphilis in five additional participants) shows the effectiveness of PrEP in preventing HIV. According to Brazilian PrEP clinical guidelines, HIV testing (whether through rapid tests, self-tests, or serological methods)

should be conducted at each follow-up visit with a healthcare professional. Regular testing for STIs is also recommended.⁶ Consistent HIV testing is essential to ensure the efficacy of PrEP and to protect the health of its users. In addition, incorporating peer educators into healthcare teams can enhance communication and encourage frequent testing among target populations of PrEP, as noted by other authors.³

The ADRs reported by 45 participants indicated that nausea was the most common symptom, highlighting a notable side effect profile. However, only two individuals discontinued PrEP due to these ADRs.

In addition, the presence of proteinuria in six individuals (despite normal creatinine levels, and elevated transaminase levels in two others) suggests some mild physiological impacts that did not result in discontinuation of the medication. However, this study has several limitations that must be considered. The reliance on self-reported data for adherence and condom use introduces potential recall and social desirability biases. The significant loss to follow-up in HIV testing (only 81 individuals evaluated at the end of the study) limits the reliability of the efficacy findings. Furthermore, the low number of individuals tested for HCV and HBV restricts a comprehensive assessment of STI incidence. Future studies should use prospective designs, objective adherence measures (e.g., pharmacological markers), and more rigorous follow-up protocols to address these gaps and provide a more accurate evaluation of PrEP outcomes.

In conclusion, this study demonstrates the effectiveness of PrEP in preventing HIV infection among high-risk populations in Ceará, Brazil, with no new HIV cases reported during the one-year follow-up period. However, the detection of syphilis cases and inconsistencies in self-reported condom use underscore the need for comprehensive sexual health education and regular STI testing alongside PrEP. While adherence to PrEP was generally high, the occurrence of ADRs and the challenges associated with daily medication adherence emphasize the importance of providing ongoing support and personalized care for PrEP users. Future interventions should focus on addressing behavioral risks, reducing stigma, and enhancing access to integrated healthcare services. This approach will help maximize the benefits of PrEP and reduce the overall burden of HIV and other STIs in vulnerable populations.

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AUTHORS' CONTRIBUTIONS

Francisco Álisson Paula de França contributed to the bibliographic research and was responsible for writing the abstract, introduction, methods, discussion, and the description and interpretation of results. He also prepared the tables, drew conclusions, conducted a review, and performed statistical analysis. **Larissa Deadame de Figueiredo Nicolete** was involved in project management and also contributed to the bibliographic research. She wrote the abstract, introduction, methods, discussion, and the description and interpretation of results, including conclusions, review, and statistical analysis.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

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