
Pharmaceutical Care Effectiveness in Brazilian Healthcare Setting: PrEP Knowledge and Adherence

Efetividade do Cuidado Farmacêutico em cenário real de saúde brasileiro: conhecimento e adesão à PrEP

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ABSTRACT

PrEP is a globally effective and safe healthcare technology that substantially reduces HIV incidence. Pharmacists have played a crucial role in promoting PrEP scale-up, however, there is a lack of studies in the Brazilian context. This intervention study, conducted in Central Brazil from 2021 to 2022, assessed pharmaceutical care's effectiveness in enhancing PrEP knowledge and adherence among high-risk individuals for HIV acquisition. Over 80% of 150 participants, were predominantly male, homosexual, averaging 31.4 years old, single, and highly educated, and showed normal liver and kidney function with no HIV seroconversions. The Intervention Group (IG) displayed significant statistical differences in PrEP knowledge ($p < 0.001$) and adherence ($p < 0.008$) compared to the control group. The clinical pharmacist effectively resolved 27 drug-related problems with no adverse effects on participants. This study is pioneering within the Brazilian context, making a significant contribution to the advancement of scientific understanding regarding the role of pharmaceutical services in fostering PrEP utilization in Brazil.

Keywords: Pre-Exposure Prophylaxis; HIV; Pharmacists; Patient Medication Knowledge; Medication Adherence.

RESUMO

A PrEP é uma tecnologia de saúde globalmente eficaz e segura que reduz substancialmente a incidência do HIV. Os farmacêuticos têm desempenhado um papel crucial na promoção da expansão da PrEP, porém, faltam estudos no contexto brasileiro. Este estudo de intervenção, realizado no Brasil Central, 2021 a 2022, avaliou a efetividade da assistência farmacêutica em melhorar o conhecimento e a adesão à PrEP entre indivíduos de alto risco para aquisição do HIV. Mais de 80% dos participantes eram predominantemente do sexo masculino, homossexuais, com idade média de 31,4 anos, solteiros e com alto nível de escolaridade, e apresentavam função hepática e renal normal, sem soroconversões para o HIV. O Grupo Intervenção (GI) apresentou diferenças estatísticas significativas no conhecimento da PrEP ($p < 0,001$) e na taxa de adesão ($p < 0,008$) em comparação ao grupo controle. O farmacêutico clínico identificou e resolveu 27 problemas relacionados com medicamentos sem efeitos adversos nos participantes. Este estudo é pioneiro no contexto brasileiro e contribui significativamente para o avanço da compreensão científica sobre o papel dos serviços farmacêuticos no fomento à utilização da PrEP no Brasil.

Palavras-chave: Profilaxia Pré-Exposição; HIV; Farmacêuticos; Conhecimento do Paciente sobre a Medicação; Adesão à Medicação.

INTRODUCTION

Pre-exposure prophylaxis (PrEP) is a healthcare technology globally adopted as an effective strategy for reducing the incidence of the human immunodeficiency virus (HIV) infection, and its effectiveness is strongly related to the rate of patient adherence (Baeten et al., 2012; Barry et al., 2023; Grant et al., 2010; McCormack et al., 2016). Since 2017, the Brazilian Public Health System has offered the antiretroviral combination of emtricitabine-tenofovir disoproxil fumarate (FTC/TDF) for use as PrEP to individuals at high risk of acquiring HIV. In 2020, the PrEP strategy was implemented in all 27 Brazilian states, and there are currently more than 60,000 users across the country (Brasil, 2023). However, access, uptake, and adherence remain the main limitations to PrEP use worldwide, particularly among a subpopulation of individuals clinically indicated for PrEP, such as transgender, cisgender women, sex workers, and people who inject drugs (PWID) (Sousa et al., 2023; Unaid, 2023).

In efforts to overcome these barriers and expand the use of PrEP, new approaches have been developed and adopted worldwide. These approaches include the introduction of new drugs (e.g., Tenofovir alafenamide-emtricitabine (F/TAF)) (The Lancet HIV, 2019), long-acting injectable formulations (e.g., cabotegravir extended-release injectable suspension), which was recently approved by the Brazilian Health Regulatory Agency (Anvisa., 2023), telehealth (Player et al., 2022; Refugio et al., 2019), protocol simplification, and diversification of PrEP prescribers for beyond physicians' orders. In Brazil, this diversification has extended to include nurses, dentists, and pharmacists, who are now allowed into PrEP prescription in public health settings (Brasil, 2022; CFF, 2021).

Pharmacists play a crucial role in expanding access to and uptake of PrEP (Brizzi et al., 2023). This field is rapidly growing, and international studies conducted in the USA, Canada, Kenya, and South Africa (Cernasev et al., 2023; Greenwell et al., 2023; MacDonald et al., 2023; Mugo et al., 2017) have demonstrated the valuable contribution of pharmacists to PrEP scale-up. Within the realm of clinical pharmacy, pharmaceutical care encompasses private consultations, medication dispensing, counseling, adverse event management, knowledge and education promotion, prescription, and the execution of laboratory tests for HIV, but also, pharmacists are increasingly involved in screening for other sexually transmitted infections (Barry et al., 2023; Booker et al., 2023; Kennedy et al., 2022). These services can be provided through in-person assistance, face-to-face consultations, or via telehealth (Greenwell et al., 2023).

There are few studies on PrEP in Brazil (e.g. Grinsztejn et al., 2018; Hoagland et al., 2017; Jalil et al., 2022; Marins et al., 2019; Torres et al., 2020; Veloso et al., 2023; Wilson et al., 2019), and our research group did not identify any pharmacist-based PrEP study design. This situation highlights a significant knowledge gap and represents a promising pharmaceutical care research area. Brazil's vast geographical expanse is served by a robust network of pharmaceutical establishments, with approximately 100,000 pharmacies that provide community assistance, public or private, distributed throughout the nation, in a scenario with almost 240,000 professionals registered in the Federal Pharmacy Council (CFF, 2021). Drawing upon well-documented literature detailing pharmacy-based initiatives to boost PrEP utilization, we hypothesize that the unique position of pharmacists as healthcare professionals in the country presents an opportunity to enhance PrEP uptake, adherence, and retention in Brazil.

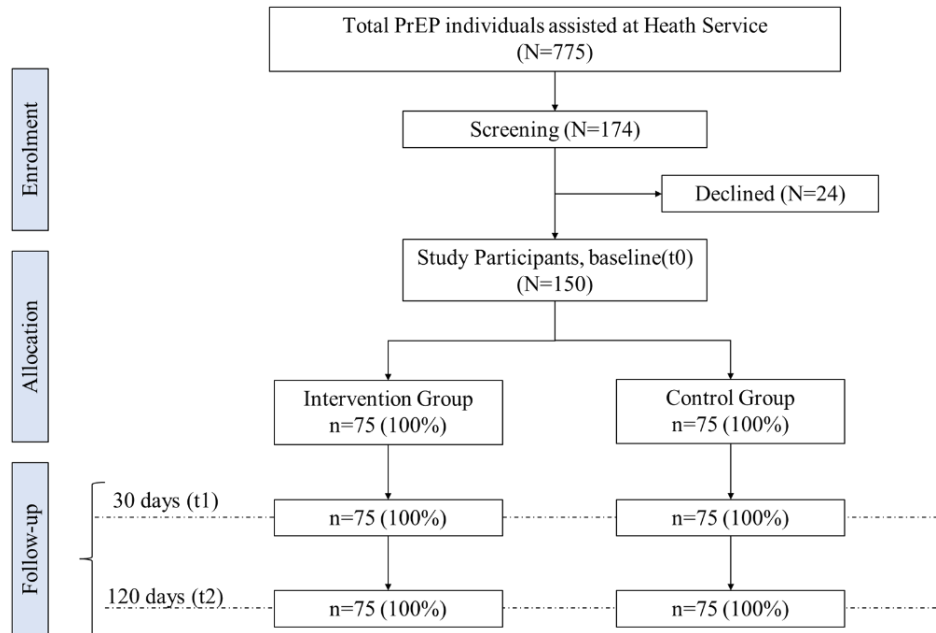
METHODS

A total of 150 individuals using PrEP was enrolled in an interventional study assembled in the city of Goiania, Goias state, central Brazil (1.5 million inhabitants estimated) (IBGE, 2023), during 2021-2022, to assess the effectiveness of pharmaceutical care related to PrEP medication knowledge and adherence. The study was conducted at an ambulatorial pharmacy located at a regional infectious diseases reference hospital where PrEP service was implemented in 2018 to assist the key population for high-risk of HIV infection, which involves men who have sex with men (MSM), sex workers, PWID and transgender, according to Brazilian Ministry of Health protocol (Brasil, 2018). The study complied with the World Medical Association Declaration of Helsinki and was approved by the Ethics Committee and registered in a national registry database of research involving human subjects. Informed consent was provided by all participants.

The study included individuals aged 18 years or over, key-populations, with negative result of HIV rapid test, elected to use daily one pill of FTC/TDF (Brasil, 2018). HIV seroconversion during study follow-up was considered the exclusion criteria. Individuals were recruited at baseline (t0) and allocated in two study groups: a) intervention group (IG), assisted

by a clinical pharmacist; b) control group (CG), that received a routine standard care. The follow-up occurred at 30 (t1) and 120 (t2) days post first assistance into health service (Figure 1).

Figure 1: Flowchart of recruitment, group allocation and follow-up of PrEP users, central Brazil, 2021 - 2022.



Participants sociodemographic, clinical, and laboratorial data were extracted by a national aggregated database (Siclom). A validated instrument (Fröhlich et al., 2010) applied at baseline and follow-up was adopted to analyze the participant's drug prescription level of knowledge, classified as insufficient; regular, or good. Medication adherence was evaluated by Morisky-Green-Levine (MGL) validated questionnaire (Morisky et al., 1986). Participants were considered with high adherence if they responded negatively to all four MGL test questions; conversely, considered with low adherence if they answered affirmatively to any of the four MGL questions.

Pharmacist Intervention Characterization

The pharmaceutical care was structured according to Descriptive Elements of Pharmacist Intervention Characterization Tool (DEPICT) version 2 (Correr et al., 2013), based on key domains: 1) contact with recipient: one-on-one contact; 2) setting of the intervention: ambulatory pharmacy; 3) focus of intervention: on a specific medical condition, specific medication class and a pre-specified sociodemographic patient's characteristics; 4) actions taken by pharmacist: provided drug information, patient counseling and monitoring results report; 5) timing of actions: occurred during patient admission,

medication dispensing and scheduled appointment. Drug-related problems (DRP) and respective planned interventions were classified according to Pharmaceutical Care Network Europe (PCNE) version V9.1 (PCNE, 2020).

Data analyzes

The Mann-Whitney U test was used for the comparison of sociodemographic variables between groups. For the race/color variable, Fisher's exact test was calculated, but also for the analysis of knowledge assessment and adherence, and to verify possible differences in the proportions between groups at recruitment (t0) and follow-up (t1 and t2). Intra-group analysis was performed using Cochran's Q test. Pairwise measures of urea and creatinine were analyzed by t-test. The nonparametric Wilcoxon test was used for aspartate aminotransferase (AST) and alanine aminotransferase (ALT) variables. Significance level of $p \leq 0.05$ was adopted. All procedures were performed in the software Statistical Package for the Social Sciences® (SPSS) version 2.2.0. and the OpenEpi Collection of Epidemiological Calculators version 3.01 (<https://www.openepi.com>).

RESULTS

A total of 150 individuals were enrolled in this study. Predominantly, they were male (90%; $n=135/150$), homosexuals (78.6%; $n=118/150$), with a mean age of 31.4 ± 7.8 years old, single (90%; $n=135/150$), presenting a high educational level (83.4%; $n=125/150$). In relation to the stratification of the key population, the majority (89.3%; $n=134/150$) consisted of MSM, with one participant identifying as transgender. None of the participants were engaged in sex work or PWID. Except for the self-declaration of race or color, which showed an unequal distribution ($p < 0.001$), no other variable presented a statistically significant difference between the participants allocated to the IG and CG, respectively (Table 1). Laboratory tests indicated normal levels of liver and kidney function. Furthermore, no cases of HIV seroconversion were observed among these individuals throughout the study period (Table 2).

Table 1. Sociodemographic Characteristics of PrEP Users at a Central Brazil Outpatient Pharmacy, 2021-2022

Characteristics	IG (n=75)	CG (n=75)	<i>p</i>
Age, mean	31.1	31.8	0.190
Genital organ of birth, n (%)			
<i>Penis</i>	65 (86.7)	70 (93.3)	0.174
<i>Vagina</i>	10 (13.3)	5 (6.7)	
Gender identity, n (%)			
<i>Man</i>	64 (85.3)	70 (93.3)	0.113
<i>Woman</i>	11 (14.7)	5 (6.7)	
Sexual orientation, n (%)			
<i>Homosexual</i>	54 (72.0)	65 (86.6)	0.085
<i>Heterosexual</i>	11 (14.7)	5 (6.7)	
<i>Bisexual</i>	10 (13.3)	5 (6.7)	
Race/color, n (%)			
<i>White</i>	21 (28.0)	47 (62.7)	< 0.001 ^b
<i>Mixed-race^a</i>	50 (66.7)	25 (33.3)	
<i>Black</i>	4 (5.3)	3 (4.0)	
Education level, n (%)			
<i>Elementary school</i>	1 (1.3)	0 (0.0)	-
<i>High school</i>	12 (16.0)	12 (16.0)	
<i>University education</i>	62 (82.7)	63 (84.0)	
Marital status, n (%)			
<i>Single</i>	56 (74.7)	58 (77.3)	0.702
<i>Married/united</i>	19 (25.3)	17(22.7)	

IG: Intervention Group; CG: Control Group; ^aMixed-race: refers to individuals with a combination of different racial background; ^bFisher exact.

Table 2. Laboratory Results of PrEP Users at a Central Brazil Outpatient Pharmacy, 2021-2022

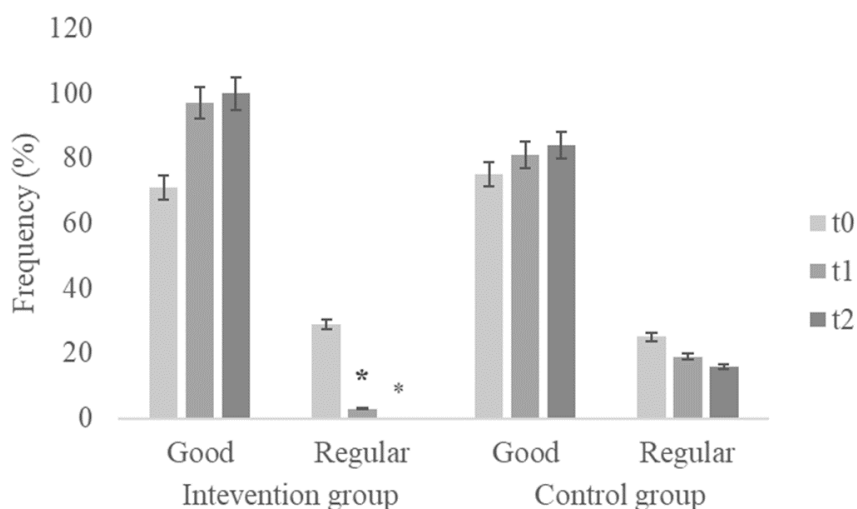
Laboratory tests	Follow-up				Δt1-t2 (mean ± dP)	
	t1		t2		IG (n=75)	CG (n=75)
	IG (n=75)	CG (n=75)	IG (n=75)	CG (n=75)		
AST(u/ml)	24.8 ± 5.99	21.14 ± 5.95	28.63 ± 5.78	29.89 ± 12.91	3.75 ± 5.79	8.75 ± 5.91
ALT(u/ml)	26.46 ± 7.02	32.72 ± 7.25	29.93 ± 5.64	26.21 ± 6.02	3.47 ± 5.38	-6.51 ± 6.31
Urea(mg/dL)	30.07 ± 9.61	28.94 ± 8.57	29.94 ± 7.57	27.71 ± 6.79	-0.13 ± 7.04	-1.23 ± 8.63
Creatinine(mg/dL)	1.05 ± 0.16	1.02 ± 0.15	1.06 ± 0.15	1.01 ± 0.15	0.01 ± 0.15	-0.01 ± 0.15

t1: 30 days PrEP; t2: 120 days PrEP; Δ: change average; dP: standard deviation; AST: aspartate aminotransferase; ALT: alanine aminotransferase; u/mL: units per milliliter; mg/dL: milligrams per deciliter; IG: Intervention group; CG: Control group.

PrEP Knowledge

At baseline, all participants, independently of the allocation group, presented a similar level of PrEP knowledge (p=0,714). However, an intragroup significant improvement was observed among in the IG, increasing from 71% (t0) to 97% (t1), and achieving 100% of satisfactory knowledge at t2 (p<0,001). At CG, a slight increase in PrEP knowledge was observed, 75% (t0) to 84% (t2). An intergroup analysis revealed a significant difference in PrEP knowledge level acquired between the IG in comparison with CG during the follow-up at t1 (p=0.003) and at t2 (p< 0.001) (Figure 2).

Figure 2. PrEP knowledge at a Central Brazil Outpatient Pharmacy, 2021-2022.



t0: baseline; t1: 30 days PrEP; t2: 120 days PrEP; *p<0,05, Fisher's exact test.

PrEP Adherence

During follow-up participants presented an increase PrEP adherence rate exhibiting a statistically significant difference between IG (98.6%) and CG (88%), respectively ($p=0.008$) (Table 3).

Table 3. PrEP Adherence Rate at a Central Brazil Outpatient Pharmacy, 2021-2022

Groups	Adherence Rate							
	t1				t2			
	n	(%)	(95%CI)	<i>p</i>	n	(%)	(95%CI)	<i>p</i>
IG (n=75)	70	93.3	85.3-97.1	0,09*	74	98.6	92.8-99.7	0,008*
CG (n=75)	64	85.3	75.6-91.6		66	88.0	78.7-93.5	

IG: Intervention Group; CG: Control Group; **p*: Fisher exact; t1: 30 days after starting PrEP; t2: 120 days after starting PrEP.

Pharmacist Intervention

A total of 27 DRPs were identified among participants at IG. Most of DRPs (96.3%; $n=26/27$) were related to dispensing errors, effectively addressed by clinical pharmacist, without any negative impact on the participants. However, one DRP classified as manifested was related to the patient's behavior involving the use of an insufficient dose of PrEP (Table 4). Planned interventions were focused on patients ($n=26$) or the medication use process ($n=1$) with the provision of verbal (74%; $n=20/27$) or written (22%; $n=6/27$) information.

Table 4. Drug-Related Problems among PrEP Users at a Central Brazil Outpatient Pharmacy, 2021-2022

DRP Classification					
Description	N=27	(%)	Occurrence	Problem (P)	Cause (C)
Insufficient dose	1	(3.7)	Manifest	P1: Treatment effectiveness	C7: Patient related C7.1: Patient intentionally uses/takes less drug than prescribed or does not take the drug at all for whatever reason
Patient does not know the name of the drugs	16	(59.3)	Potential	P1: Treatment effectiveness	C5: Dispensing C5.2: Necessary information not provided or incorrect advice provided
Patient does not know about the adverse effects	5	(18.5)	Potential	P2: Treatment safety	C5: Dispensing C5.2: Necessary information not provided or incorrect advice provided
Patient does not know about drug interactions	4	(14.8)	Potential	P1: Treatment effectiveness or P2: Treatment safety	C5: Dispensing C5.2: Necessary information not provided or incorrect advice provided
Patient does not know how to store the medicine	1	(3.7)	Potential	P1: Treatment effectiveness	C5: Dispensing C5.2: Necessary information not provided or incorrect advice provided

DISCUSSION

Currently, in Brazil, approximately 65,000 PrEP users are served by the Public Health System, with more than 2,000 individuals (3.6%) assisted in Goiás state, a study setting, located in Central Brazil (Brasil, 2023). During the study period in 2021, the total number of participants represented 16% of all people who started PrEP in Goiás that year. The characterization of these individuals revealed that most PrEP users were young adults, MSM, and had a high degree of education, which aligns with the national scenario. The data also corroborate with the low representation of sex workers, PWID, and transgender individuals among those with access to PrEP (Brasil, 2023).

Adherence to PrEP is crucial for its effectiveness, and several factors can influence it, including knowledge about pharmacotherapy (Sidebottom et al., 2018). In our study, participants presented a satisfactory level of knowledge about PrEP at baseline. However, only those who received the clinical pharmacist intervention achieved a significant increase in PrEP knowledge at the end of the follow-up. Therefore, we believe that pharmaceutical services, especially those aimed at the population with high social

vulnerability and high risk of HIV infection, can contribute to overcoming the inequity of access and adherence to PrEP.

Perceptual variables significantly impact the rates of acceptance and adherence to PrEP, and they can be effectively mitigated through the enhancement of communicative interactions between healthcare providers and patients (Arnold-Forster et al., 2022; Horne et al., 2005). However, despite the importance of PrEP knowledge for adherence, much of the digital collection on the theme is associated with the evaluation of healthcare professionals' knowledge about eligibility criteria and safe usage standards of therapy (Broekhuis et al., 2018; Burns et al., 2023; Karabatsos et al., 2023; Pratt et al., 2022). In this context, the present study is innovative in evaluating PrEP users' knowledge about their pharmacotherapy.

Several methods can be used to evaluate PrEP adherence, including direct and indirect methods. The scientific literature demonstrates a positive correlation between the use of these methods, preserving their sensitivity and specificity (Marins et al., 2019). In our study, a significant increase in the PrEP adherence rate was achieved by those with pharmaceutical intervention, which was evaluated by an indirect method. Therefore, studies with robust designs to evaluate the effectiveness and safety of interventions (Berger et al., 2010) that directly impact PrEP adherence are of great importance, given the high impact of HIV infections and AIDS on global health (Unaid, 2023).

Among the study participants, there was no HIV seroconversion, and no significant laboratory alterations were identified in the markers of hepatic and renal function. These findings corroborate the international literature data on the efficacy and safety of PrEP use (Mugwanya & Baeten, 2016) linked to high rates of adherence to pharmacotherapy (Grinsztejn et al., 2018; Hoagland, 2016; Marins et al., 2019; Wilson et al., 2019). It is also worth noting that the findings of this study are in line with the scientific evidence that deals with the clinical profile of PrEP users, who, in general, are young adults who do not present underlying diseases or comorbidities (Grinsztejn et al., 2018; Kibengo et al., 2013; Luz et al., 2018). Despite the short follow-up period of PrEP users, which is a limitation of this study, positive impacts on humanistic outcomes (knowledge and adherence) were observed. In this context, we believe that new studies are important to evaluate PrEP adherence in the long term.

Drug-related problems were identified in this study. However, we highlighted that all problems were managed and resolved during clinical pharmacy consultation and did not cause harm to patients. In Brazil, several strategies and policies have been implemented

to promote patient-centered pharmaceutical practice to achieve the best results with pharmacotherapy, including initiatives from the Brazilian Federal Pharmacy Council and public policies that support pharmaceutical services (Brasil, 2004; Brasil, 1998; CFF, 2013, 2016). This study also meets the recent federal government measure that determined the inclusion of the pharmacist in the list of PrEP and Post-Exposure Prophylaxis (PEP) prescribers, within the scope of the public health system. This action integrates initiatives that aim to promote greater democratization of access to pharmacological strategies for preventing HIV infection throughout the country.

CONCLUSION

This study demonstrated the effectiveness of an intervention conducted by a clinical pharmacist, targeting individuals at a higher risk of HIV exposure. The intervention had a significant impact on improving the evaluated outcomes: PrEP knowledge and adherence rates. During a pharmaceutical consultation conducted in a private setting, DRPs mostly related to medication dispensing, were identified, and resolved without causing harm to the patients. Additionally, the monitoring of clinical and laboratory parameters confirmed the safety and efficacy of PrEP use in the study population. As adherence is crucial for the long-term effectiveness of oral PrEP, we emphasize the importance of conducting studies with extended follow-up in the Brazilian context.

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