

Background

- Reports of worrisome trends in HIV incidence among men 15-19 years old in Brazil, specially among key adolescent population, moved a new agenda for inclusion of adolescents in the Pre-Exposure Prophylaxis (PrEP) Program of the National Health System (PrEP-SUS).
- We aimed to evaluate the adherence, safety, and feasibility of PrEP in real-world settings among adolescent men who have sex with men (aMSM) and transgender women (aTGW).

Methods

- PrEP1519 is a single-arm, demonstration cohort study of daily TDF/FTC as PrEP among aMSM and aTGW aged 15-19 years.
- It was conducted in three Brazilian cities (Salvador, Belo Horizonte and São Paulo) and eligible were those HIV uninfected, at high risk of HIV, and with no risk of kidney and liver damage. Follow-up data is from February 2019-February 2021 (i.e., 96 weeks).
- Study visits occurred at baseline, weeks 4, 12, and then quarterly.
- Demographic and sociobehavioural data were collected by a questionnaire.
- A mixed logistic model for longitudinal data evaluated the factors associated with high adherence, measured by medication possession ratio (i.e., MPR ≥ 1).
- For this analysis, we included participants who had a minimum of 2 consecutive visits and used PrEP at least once during follow-up.

Results

- The intention-to-treat population included 713 adolescents who initiated PrEP.
- Most MSM (91.9%), 18-19 years old (yo) (80.8%), self-identified as black/brown (69.7%).

HIV incidence

- Incident HIV infection occurred in nine participants:
 - Overall incidence rate (IR) = **1.64 per 100 person-years**; (95%CI: 0.50-2.78)
 - Three incident HIV infections among those aged 15-17 yo:
 - Incidence rate = **3.35 per 100 person-years** (95%CI: 0.50–7.19)
 - Five incident HIV infections among those aged 18-19 yo
 - Incidence rate **1.26 per 100 person-years** (95%CI: 0.15–2.36)
 - All seroconverters had TFV-DP dosages < 400fmol/punch, equivalent to the use of fewer than 3 tablets per week (Figure 2).

PrEP adherence

- Most had moderate (MPR = 0.53-1.00) and high (MPR ≥ 1) adherence to PrEP. High adherence decreased over the follow-up weeks (Figure 3).
- Multivariate analysis showed that high adherence (MPR ≥ 1) was higher among those with higher number of sexual partners, who perceived themselves at high risk of HIV infection, living with parents or other family member, and most likely among aMSM (vs. aTGW), but the confidence interval was wide and imprecise (Table 1).

Safety

- There were rare laboratory abnormalities identified during follow-up.
- There was no significant increase in creatinine clearance and two participants had grade III TGO-AST.
- 496 reported at least one sign or symptom while using PrEP (69.6%), disappearing during follow-up (Table 2).
- None of the participants using PrEP showed changes in ASL/ALT and TFG markers at a grade IV level of impairment during follow-up.

Figure 1. Consort type diagram of aMSM and aTGW enrollment in PrEP1519 cohort. February 2019 to February 2021.

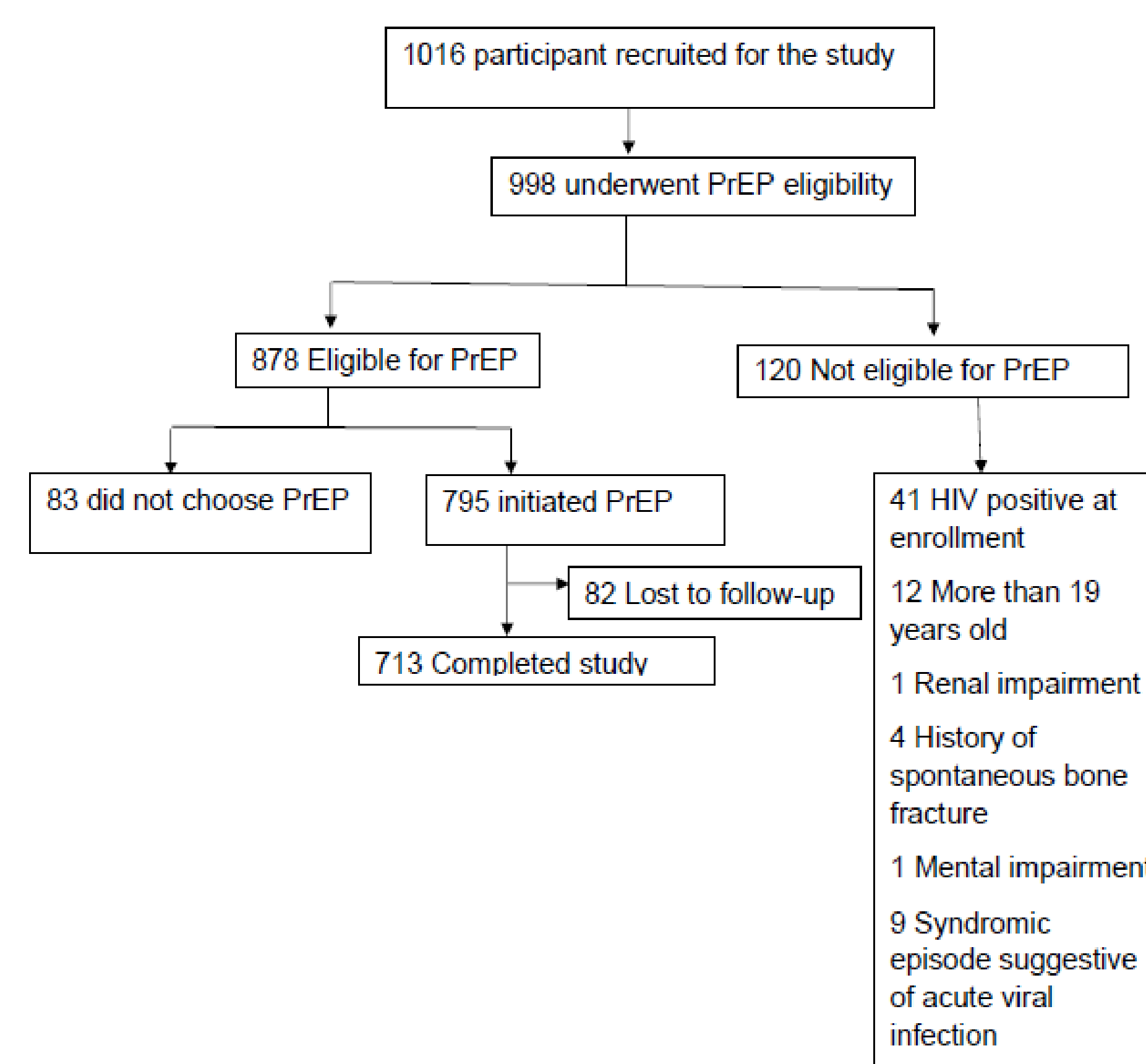


Figure 2. Tenofovir diphosphate levels in DBS samples of participants who seroconverted during follow-up. PrEP1519 Cohort, Brazil, February 2019 to February 2021

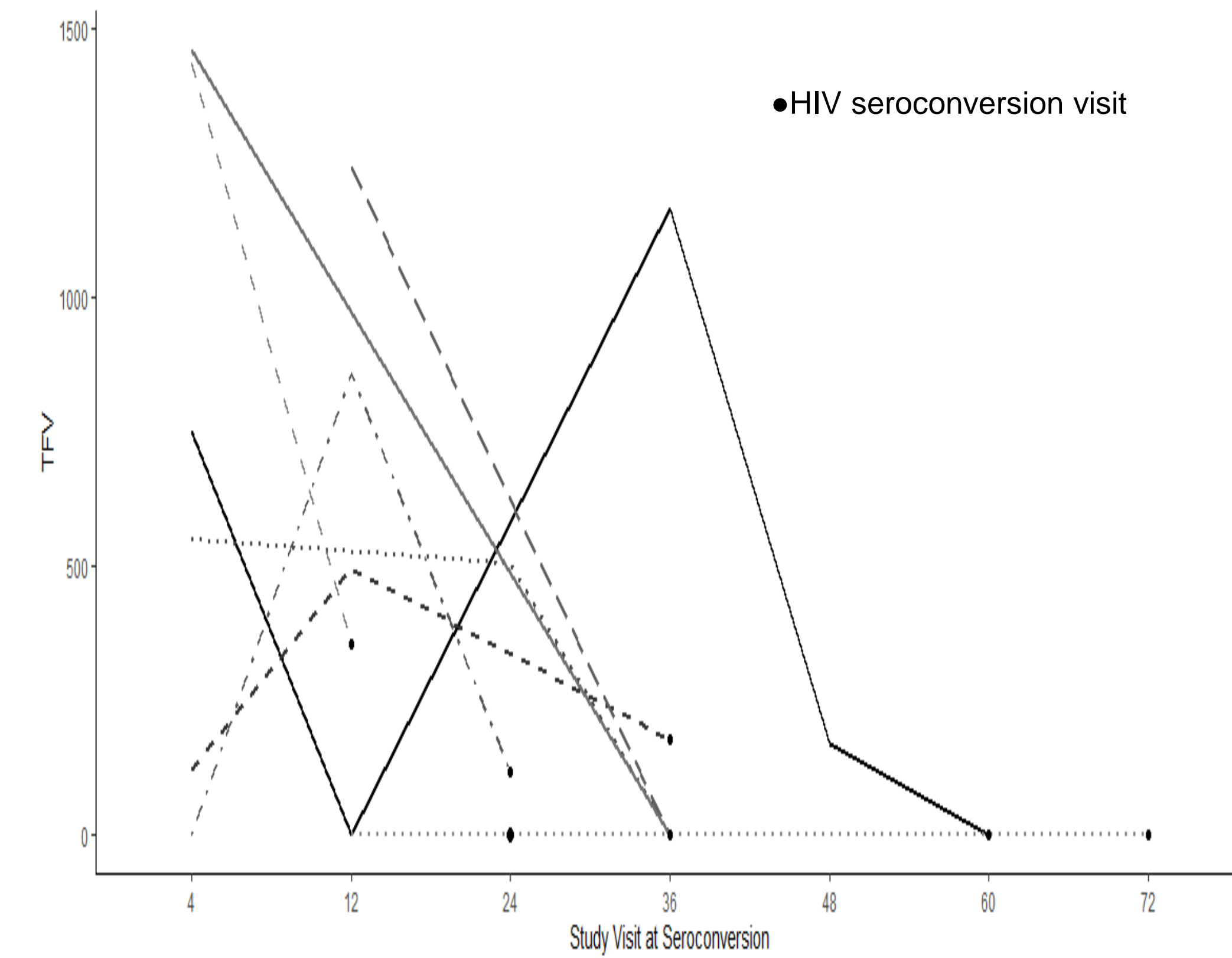


Figure 3. Weekly MPR among aMSM and aTGW from week 04 to 96 in the PrEP1519 Cohort, Brazil, February 2019 to February 2021*.

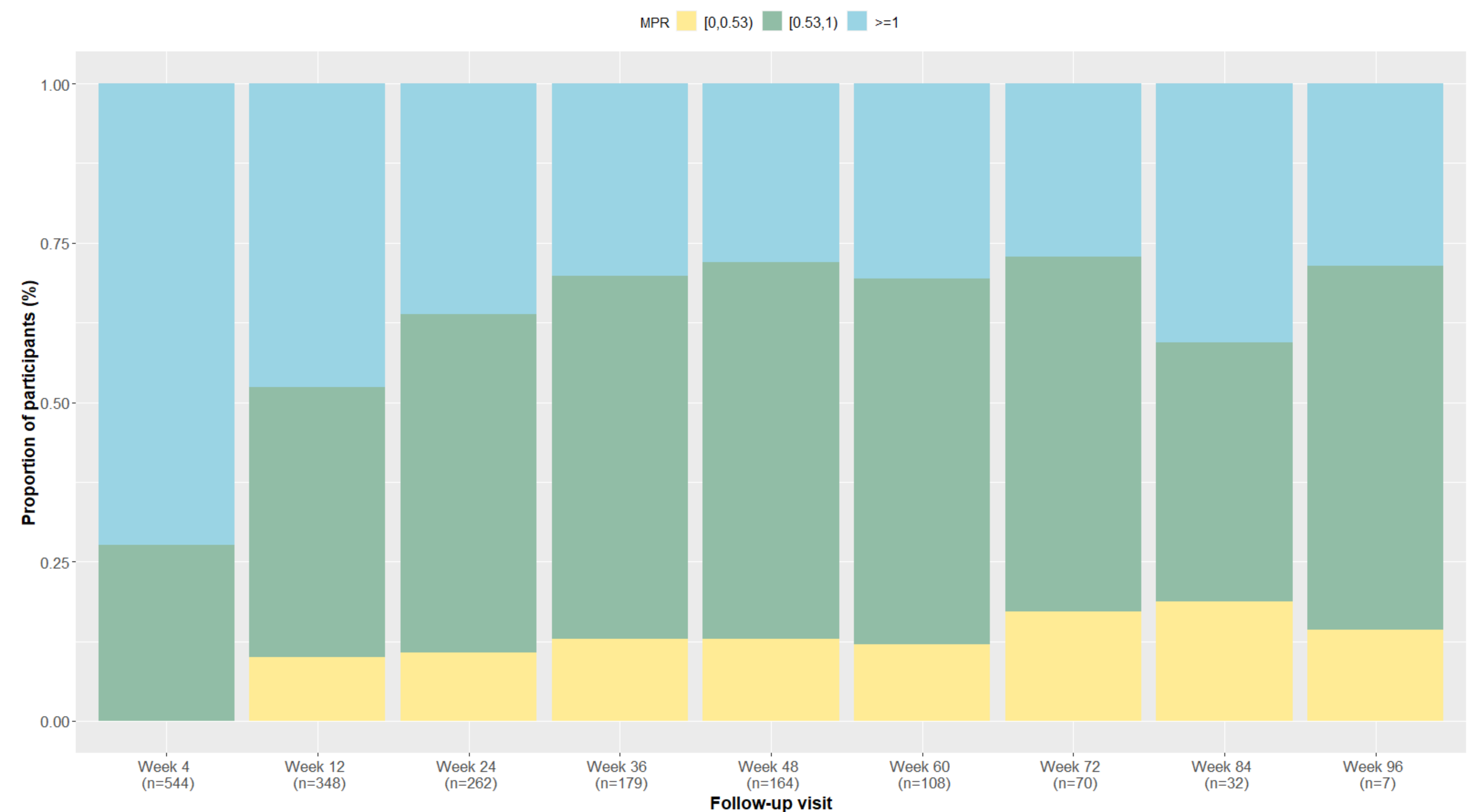


Table 1. Multivariate analysis of factors associated with high MPR compared to low/moderated. PrEP1519 Cohort, Brazil, February 2019 to February 2021

Variables	MPR ≥ 1	
	OR*	95% CI
Population groups		
aTGW	1.00	
aHSH	1.29	0.63 - 2.63
Age		
15 a 17 yo	1.00	
18 a 20 yo	0.68	0.41 - 1.11
Race/skin color		
Non-blacks	1.00	
Blacks	0.69	0.45 - 1.04
Number of male sexual partners in the last 6 months**		
0-5	1.00	
6 or more	1.51	1.00 - 2.30
Perceived risk of HIV infection		
Low	1.00	
Moderate	1.48	0.95 - 2.30
High	1.87	1.11 - 3.15
Housing situation		
Don't live with their parents or relatives	1.00	
Live with their parents or relatives	1.69	1.03 - 2.79

* Adjusted for a COVID19 period indicator (pre and during quarantine measures)
**Time-dependent variable

Table 2. Events in participants during follow-up. PrEP1519 Cohort, Brazil, February 2019 to February 2021

Symptoms and Signs	N		%
	Total	100.0	
Nausea	140	28.23	
Headache	96	19.35	
Diarrhea	90	18.15	
Abdominal pain	57	11.49	
Flatulence	45	9.07	
Vomits	19	3.83	
Fatigue	18	3.63	
Dizziness	13	2.62	
Insomnia	11	2.22	
Rash	7	1.41	
Total	496	100.0	
Laboratory Events			
AST (U/L)	45	22.7	
ALT (U/L)	70	35.4	
Creatinine clearance (ml/min)	83	41.9	
Total	198	100.0	

Conclusions

IR was high among young adolescents enrolled in PrEP. But, lower when compared to an IR of 7.8% among MSM and TGW aged 30 years or less tested in Rio de Janeiro. PrEP adherence seems lower among aTGW, indicating the need for greater monitoring and care for TGW. Oral PrEP was safe among aMSM and aTGW. Effective PrEP use must consider that adolescents are dynamic and fluid and, therefore, continually adapt to their context to improve adherence to PrEP.

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