HepHIV 2026
by EuroTEST
2-3 NOVEMBER·DUBLIN

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Efficacy of an Online HIV/STI Screening Addressed to Men Who Have Sex with Men Users of PrEP in Spain (TESTATE PrEP)

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OBJECTIVES

HIV disproportionately impacts key populations globally, including gay, bisexual, and other men who have sex with men (GBMSM). In Spain, pre-exposure prophylaxis (PrEP) has been included in the service portfolio since 2019; however, quarterly in-person follow-ups drive healthcare burden and waitlists. Digital strategies such as self-sampling and internet-based HIV and sexually transmitted infection testing may reduce barriers and improve retention in care. This study assessed the efficacy of the TESTATE PrEP intervention, a hybrid follow-up model, alternating online and face-to-face visits, in reducing the healthcare burden while maintaining retention in PrEP care among GBMSM in Spain.

METHODS

The TESTATE PrEP trial (NCT05752643) is a non-inferiority randomized controlled trial at the Drassanes Vall d'Hebron Center in Barcelona, with 218 individuals randomized 1:1 to an experimental arm with alternating online and in-person PrEP follow-ups or a control arm with quarterly in-person visits. Healthcare burden was assessed with the Mann–Whitney U test. The primary retention analysis used a 10% non-inferiority margin. Retention was also compared using Fisher's exact test in overall and adjusted analyses, the latter excluding withdrawals not attributable to the study.

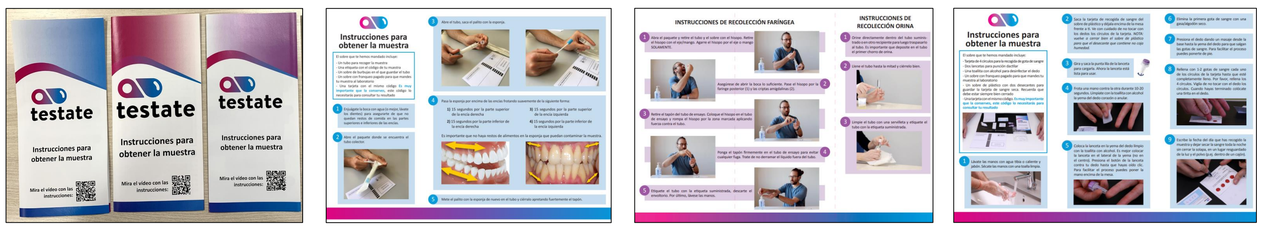

Figure 1. Instructions for self-sampling (oral fluid for HIV; urine and pharyngeal and anal swabs for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*; dried blood spots for syphilis).

RESULTS

From May 2023 to August 2025, 208 (95.4%) cisgender men, 9 (4.1%) non-binary individuals, and 1 (0.5%) transgender woman were included. Median age was 36 years. The intervention reduced total visits per participant (median 5 vs 9, p < 0.001. Unscheduled visits were comparable (median 2 in each arm, p = 0.684, Figure 2). After adjustment, retention in care was 87.2% in the control arm and 76.1% in the experimental arm. Although the difference between arms was not statistically significant (p=0.053, Figure 3), the 95% confidence interval crossed the 10% margin, so non-inferiority was not demonstrated. In the unadjusted analysis, retention was lower in the experimental arm than in the control arm (64.2% vs 79.8%, p=0.015).

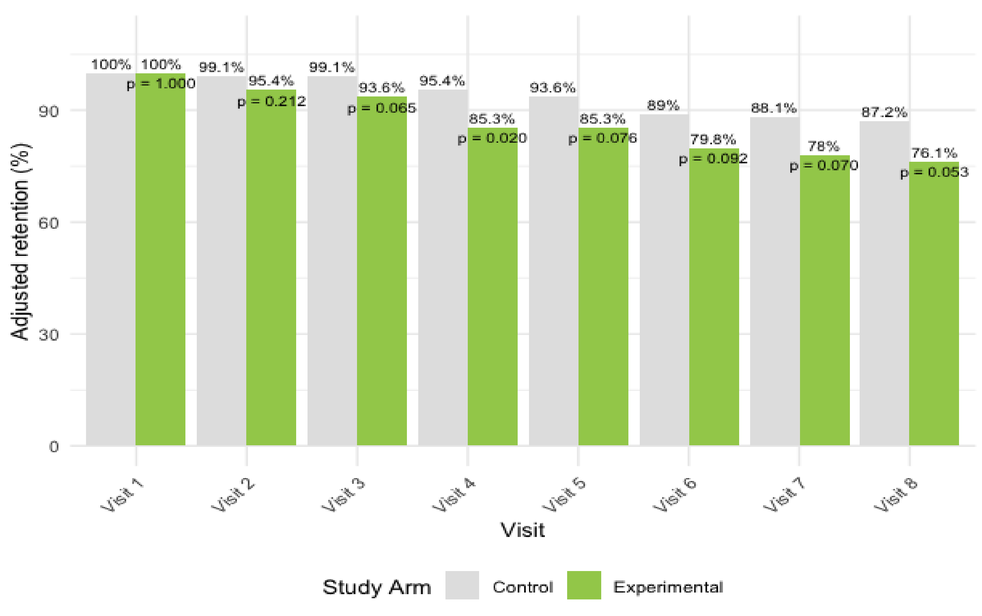

Figure 2. Retention at each follow-up visit among participants in the control and experimental arms of the TESTATE PrEP study (May 2023–August 2025, Barcelona, Spain; N=218), after adjustment for study-related reasons for withdrawal.

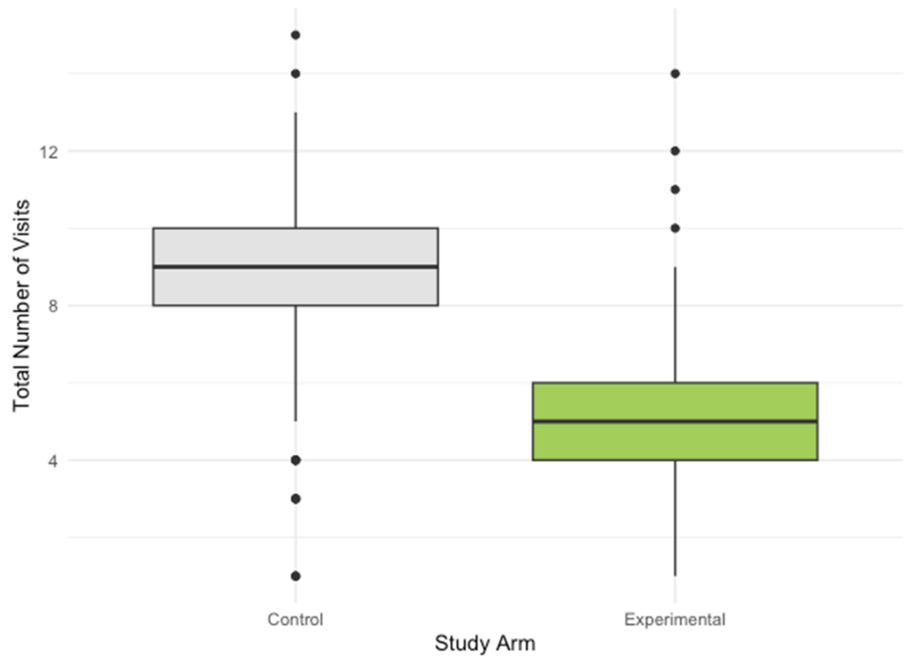

Figure 3. Distribution of scheduled and unscheduled face-to-face visits per participant in the control and experimental arms of the TESTATE PrEP study (May 2023–August 2025, Barcelona, Spain; N=218).

CONCLUSIONS

The TESTATE PrEP trial shows that a hybrid model, alternating online and face-to-face visits, substantially reduces healthcare burden by decreasing scheduled face-to-face visits without increasing unscheduled visits. Although non-inferiority for retention in PrEP care was not demonstrated, hybrid follow-up may still represent a complementary rather than universal replacement for conventional PrEP care. Overall, the results support the integration of digital strategies into PrEP services, with the potential to increase service capacity, improve access to PrEP, and optimize healthcare resource utilization. Further research is needed to assess long-term effectiveness and scalability of this model across different healthcare settings.

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