Simplified Access and Retention Model for Vulnerable People With HIV: SIMPLIFIED Study Results

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Background: HIV virological suppression in vulnerable populations is influenced by various social determinants of health that affect access to healthcare. This study evaluates the feasibility and efficacy of a "test, treat, and retain" strategy implemented via street teams and a mobile unit using BIC/FTC/ TAF.

Methods: A clinical trial conducted in Madrid/Spain in 2023-2024 that included vulnerable individuals >18 years with HIV, both ART-naive and pre-treated participants who had discontinued ART. Recruitment occurred in non-hospital settings, primarily on the streets by NGO street teams and a mobile unit. Participants-initiated ART at the same day and were followed for 48 weeks. During this period, they received social support to encourage attendance at follow-up visits and collect ART at the pharmacy.

Results: 101 participants were included, median age of 34 years, 86.1% male, and predominantly Hispanic (73.3%). Sixty-three percent had unstable home, with 25% being homeless. 44% had problematic drug use in the last year. Thirty percent had never taken ART, and 70% had discontinued it (average of 6.9 months), with 9% showing previous virological failure). The prevalence of at least one resistance mutation at baseline was 32.9% (26/79) (2.5% NRTI, 24.1% NNRTI, and 3.8% PI). The median CD4 nadir was 352 (236-500). Retention rate at week 48 was 64.4%, with main reasons for non-retention being loss to follow-up (19.8%), relocation to another city (5.9%), and incarceration (5%). ART adherence was incomplete in 57.3% of participants, and 10.1% had interrupted ART more than 20 days during at least one of their visits. In the per-protocol analysis, by week 48, 96.9% of patients achieved a viral load < 50 copies/ml. Of these, two patients had discontinued ART by the time of their 48-week visit; however, no virological failures were observed during the study. In the multivariate analysis, acquisition of HIV through injection drug use was associated with lower retention in HIV care [ORa 6.1 (95% CI 1.75-21.3) p = 0.005]. Adverse events were reported in 68.3% of patients, though none required drug withdrawal, and 95.3% were of mild intensity.

Conclusions: The feasibility of a "test, treat, and retain" strategy, combined with BIC/FTC/TAF, proved to be effective in achieving and maintaining viral suppression, despite challenges related to adherence and interruptions in ART. New models of HIV care should emphasize social support to improve retention in care for people with HIV from injection drug use.