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## BACKGROUND

Globally, 39 million people live with HIV, with 1.3 million new annual infections (1). Despite progress and declining diagnoses, challenges persist in testing, treatment initiation, adherence, retention, and viral suppression, affecting vulnerable populations particularly. Currently, 10% of individuals on ART fail to achieve viral suppression (2). Same-day ART initiation accelerates viral suppression, improves adherence, and reduces transmission. BIC/FTC/TAF, with high efficacy, favorable resistance profile, and once-daily dosing, is optimal for rapid initiation (3). The SIMPLIFIED Study (4) utilizes mobile units for real-time screening, confirmatory testing, and immediate ART initiation in marginalized groups, integrating social support and pharmacy assistance to improve retention.

## METHODS

**Design & Setting:** Prospective, single-center, phase IV clinical trial in Madrid (2023–2024). Mobile outreach via specialized van providing point-of-care HIV testing and same-day ART initiation.

**Population:** Vulnerable adults (≥18 yrs, including drug users, homeless, undocumented immigrants) with confirmed HIV and detectable viral load.

**Primary outcomes:** Retention in care at 48 weeks, viral suppression (HIV-RNA 50 copies/mL, per protocol analysis).

**Secondary outcomes:** Time to ART initiation, adverse events, genotypic resistance (upon treatment failure), patient-reported acceptability and feasibility.

**Recruitment & Screening:** Mobile unit outreach (streets, shelters, community centers) with nonjudgmental approach. Counseling on prevention, transmission, ART importance. Rapid HIV testing (capillary), confirmation via laboratory test. Informed consent obtained.

**Intervention (“Test, Treat & Retain”):** Same-day ART initiation (single tablet BIC/FTC/TAF). Social support includes transportation/accompaniment, on-site or pharmacy-dispensed medication, and regular follow-up (calls/visits). Follow-up duration: 48 weeks.

The same-day "Test, Treat & Retain" strategy using BIC/FTC/TAF demonstrated high virologic suppression rates in a vulnerable population, despite significant retention and treatment adherence challenges

Mobile outreach models, combined with simplified ART strategies, can effectively engage marginalized populations. However, addressing social determinants of health—including housing instability and substance use—remains crucial for long-term retention in HIV care.

## RESULTS

101 participants were included. Recruitment occurred in non-hospital settings, primarily on the streets.

### Baseline Characteristics of Participants N=101

Characteristic	n (%) or Mean ± SD
Age (years)	34 (28–44)
Male	87 (86.1)
Race	
Caucasian	26 (25.7)
Hispanic	74 (73.3)
Born outside Spain	79 (78.2)
University education	14 (14.7)
Sexual Orientation	
Homosexual	57 (57.6)
No Social Support	68 (67.3)
No Right to Healthcare	82 (82.0)
Barriers to Healthcare Access	88 (87.1)
Housing Status	
Homeless	63 (62.4)
Street living	16 (25.4)*
Unemployed	86 (86.9)
Problematic Alcohol Use	14 (13.9)
Drug Use	44 (43.6)
Cocaine	28 (68.3)
Heroin	13 (32.5)
Methamphetamine	5 (13.2)
Injected drug use	18 (40.9)

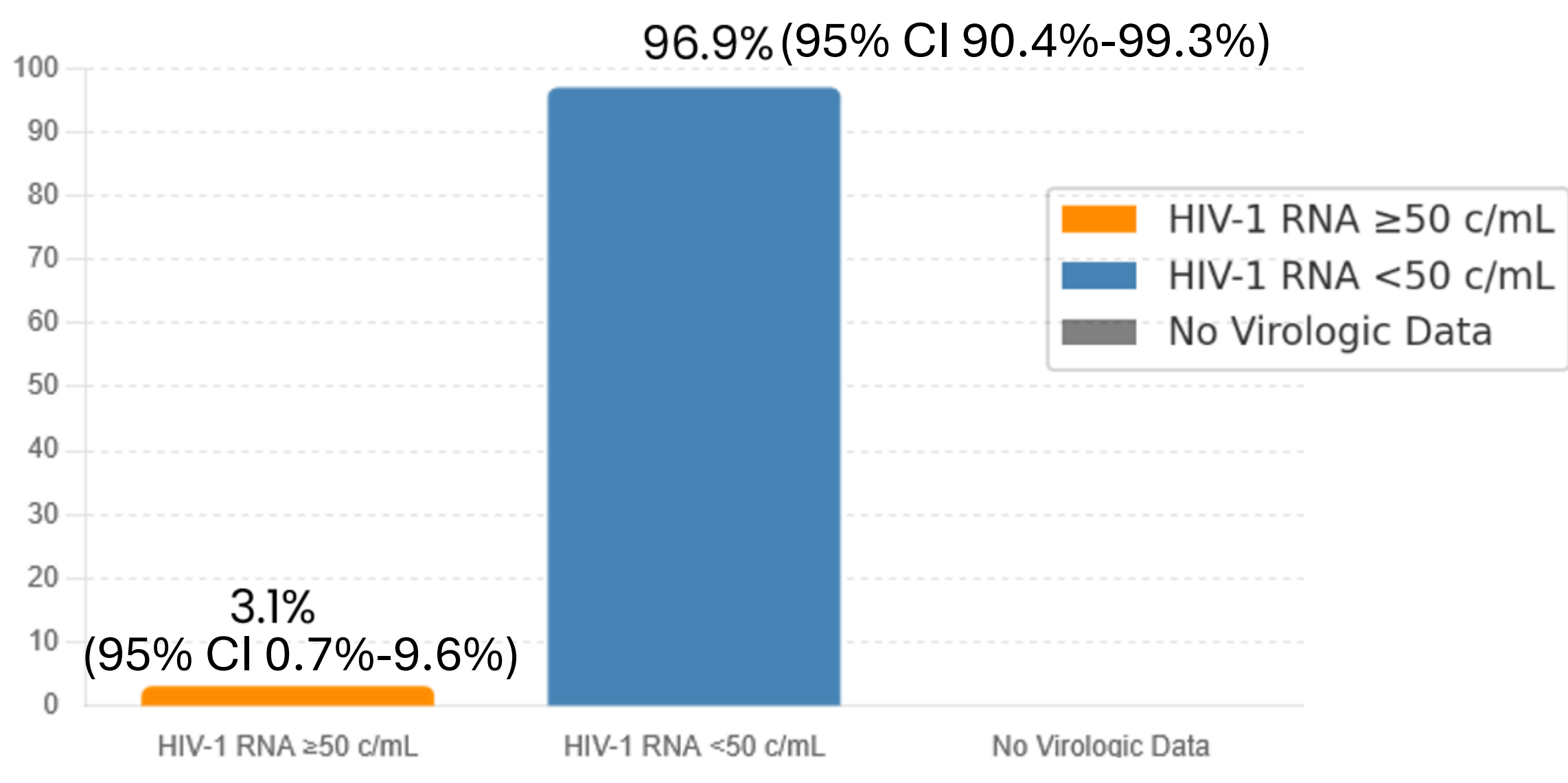
### Adherence

Parameter	n	% total N*	% of Non-Adherent
<b>Overall Treatment Adherence</b> (of those with complete data)			
Fully adherent (Yes)	38	42.70%	
Non-adherent (Missed ≥1 visit)	51	57.30%	
<b>Non-Adherent Visits</b> (in how many of all conducted visits did the patient forget to take the medication?)			
None	38	42.70%	--
>0 to <50% non-adherent visits	25	28.10%	49.00%
≥50% non-adherent visits	26	29.20%	51.00%
<b>Maximum Missed Doses per Month</b>			
None	38	42.70%	--
Up to 10 missed doses	39	43.80%	76.50%
11–20 missed doses	3	3.40%	5.90%
21–30 missed doses	9	10.10%	17.60%

Among patients who are non-adherent in 50% or more of the visits, the majority are Spanish and have problematic alcohol use.

### Virologic Efficacy at week 48

Modified analysis to exclude individuals who were not retained in care



### Factors associated with lower retention in care

Factor	OR (95% CI), p-value
Age (years)	0.99 (0.95 - 1.02), p=0.472
Born in Spain	0.28 (0.11 - 0.76), p=0.012
Right to healthcare	0.35 (0.12 - 0.99), p=0.049
Transmission: IDU	0.15 (0.04 - 0.51), p=0.003
Drug use (Non-IDU vs. IDU)	4.50 (1.24 - 16.28), p=0.022
Active drug use	0.43 (0.19 - 0.98), p=0.046
Positive HCV serology	0.18 (0.07 - 0.47), p=0.001
Years with HIV	0.95 (0.91 - 0.99), p=0.022
Nadir CD4	1.00 (1.00 - 1.00), p=0.032
Previous ART failure (No failure vs. failure)	7.94 (0.85 - 73.9), p=0.069

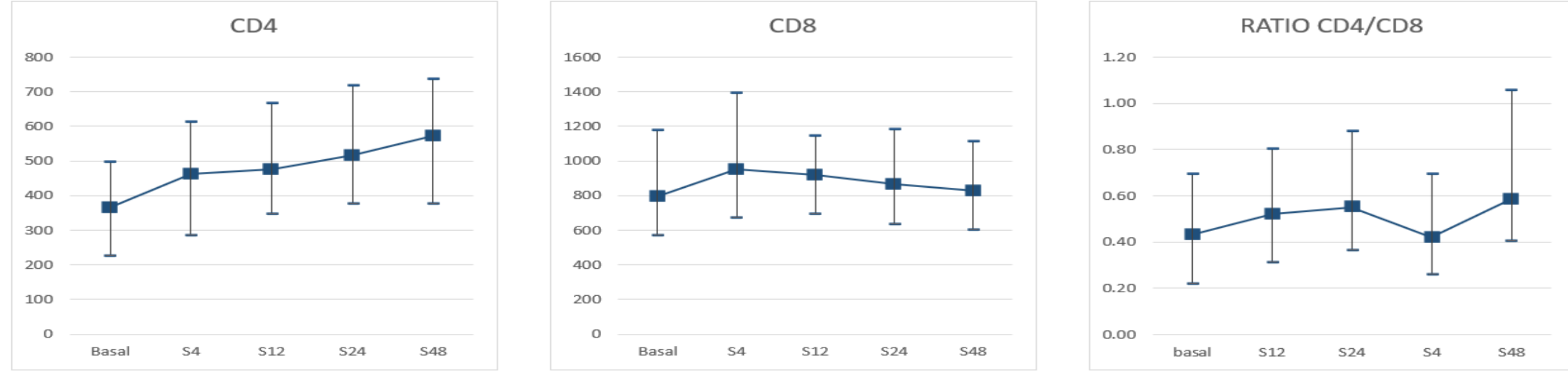
In the multivariate analysis, acquisition of HIV through injection drug use was associated with lower retention in HIV care **aOR 6.1 (95% CI 1.75–21.3) p = 0.005.**

### Adverse events

Characteristic	Result
<b>Total AEs</b>	192
<b>Participants with AEs</b>	69/101 (68.3%)
<b>Serious or Life-Threatening</b>	1 exitus (0.5%), 1 life-threatening event (0.5%), 3 hospitalizations (1.6%)
<b>AE Intensity</b>	Mild: 183 (95.3%) Moderate: 8 (4.2%) Severe: 1 (0.5%)
<b>Drug Relationship</b>	2 events (1.0%) deemed related to the study drug 190 events (99.0%) unrelated
<b>Outcome</b>	- No AE led to permanent discontinuation - 82.9% resolved - 17.1% ongoing at data cutoff

**Incidence of Adverse Events**

- 68.3% of participants reported at least one adverse event.
- 95.3% of these were mild; none required permanent discontinuation of BIC/FTC/TAF.



CD4 cell/mm3 changes from baseline

## CONCLUSIONS

The same-day "Test, Treat & Retain" strategy using BIC/FTC/TAF demonstrated high virologic suppression rates (96.9%) in a vulnerable population, despite significant retention challenges.

At Week 48, 64.4% of participants remained in care. The main barriers to retention were loss to follow-up (19.8%), relocation (5.9%), and incarceration (5.0%).

Same-day ART initiation was achieved in all eligible patients. However, 57.3% of participants had incomplete adherence, and 10.1% had treatment interruptions >20 days. No cases of virologic failure were observed.

The intervention was highly accepted, with over 95% satisfaction reported in most categories, including ease of access, support from the healthcare team, and adherence assistance.

## ADDITIONAL KEY INFORMATION

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### SIMPLIFIED GeSIDA I2221 Study

The sponsor of the trial is the **SEIMC-GESIDA Foundation**.

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