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BACKGROUND

DTG/3TC and BIC/FTC/TAF are recommended ART regimens in major HIV guidelines. However, data on the metabolic and inflammatory effects of switching from DTG/3TC to BIC/FTC/TAF are scarce. We investigated the impact of this switch on metabolic parameters and systemic inflammation in virologically suppressed individuals.

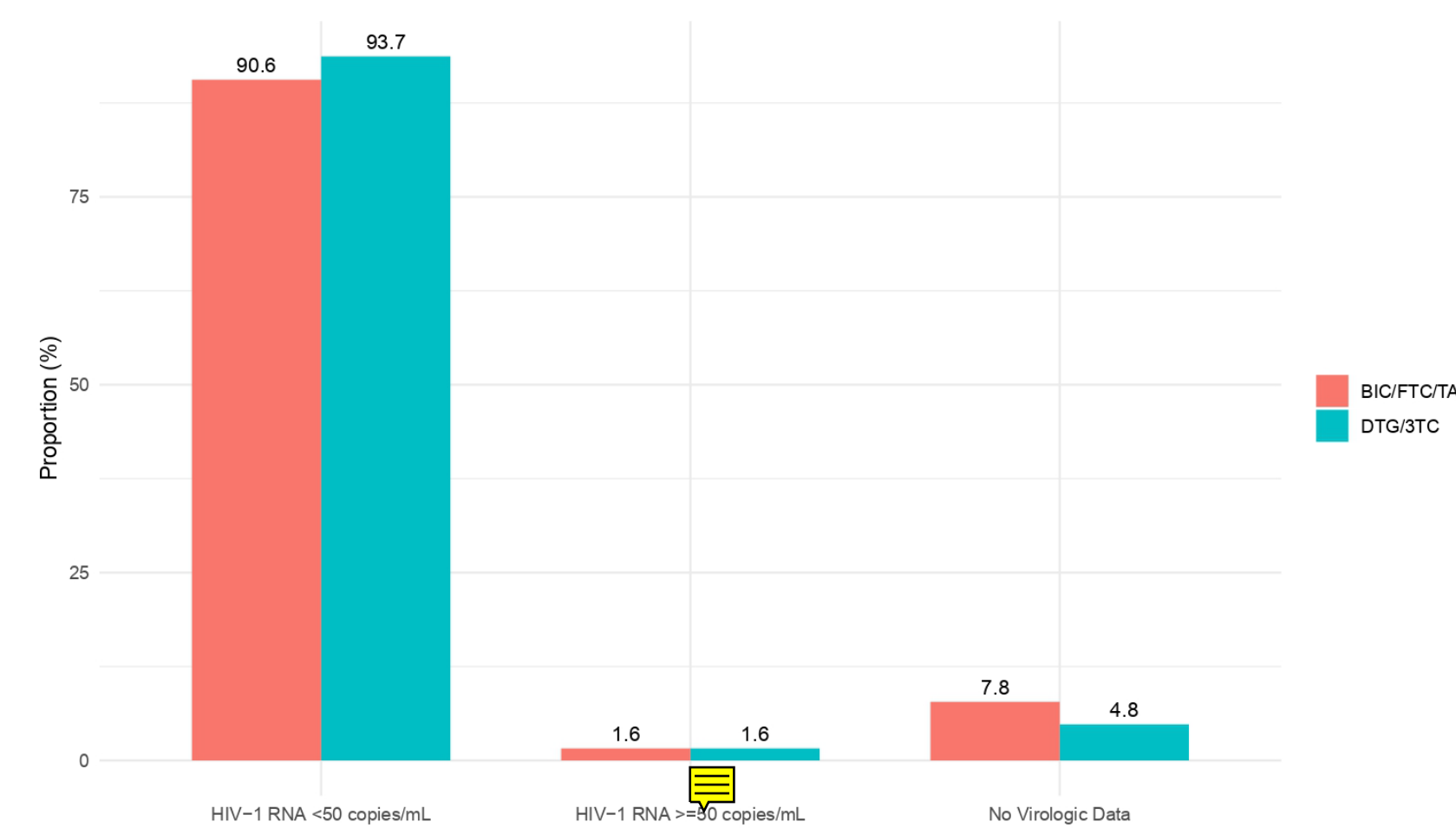
METHODS

- Randomized, open-label, multicenter INSTINCT trial (clinicaltrials.gov: NCT04076423). We evaluated the effect of switching from DTG/3TC to BIC/FTC/TAF vs. remaining on DTG/3TC on systemic inflammation up to 96 weeks. We included 141 participants. Participants were adults with confirmed, virologically suppressed HIV, on stable ART with DTG/3TC for a minimum of 48 weeks.
- We focused on IL-6 changes from baseline to week 96 using high-sensitivity ELISA (Kit Human IL-6 HS Bio-technique®).
- Statistics: Estimated treatment effects compared using linear mixed models, including interaction terms and treatment and time interaction terms in Stata v.18

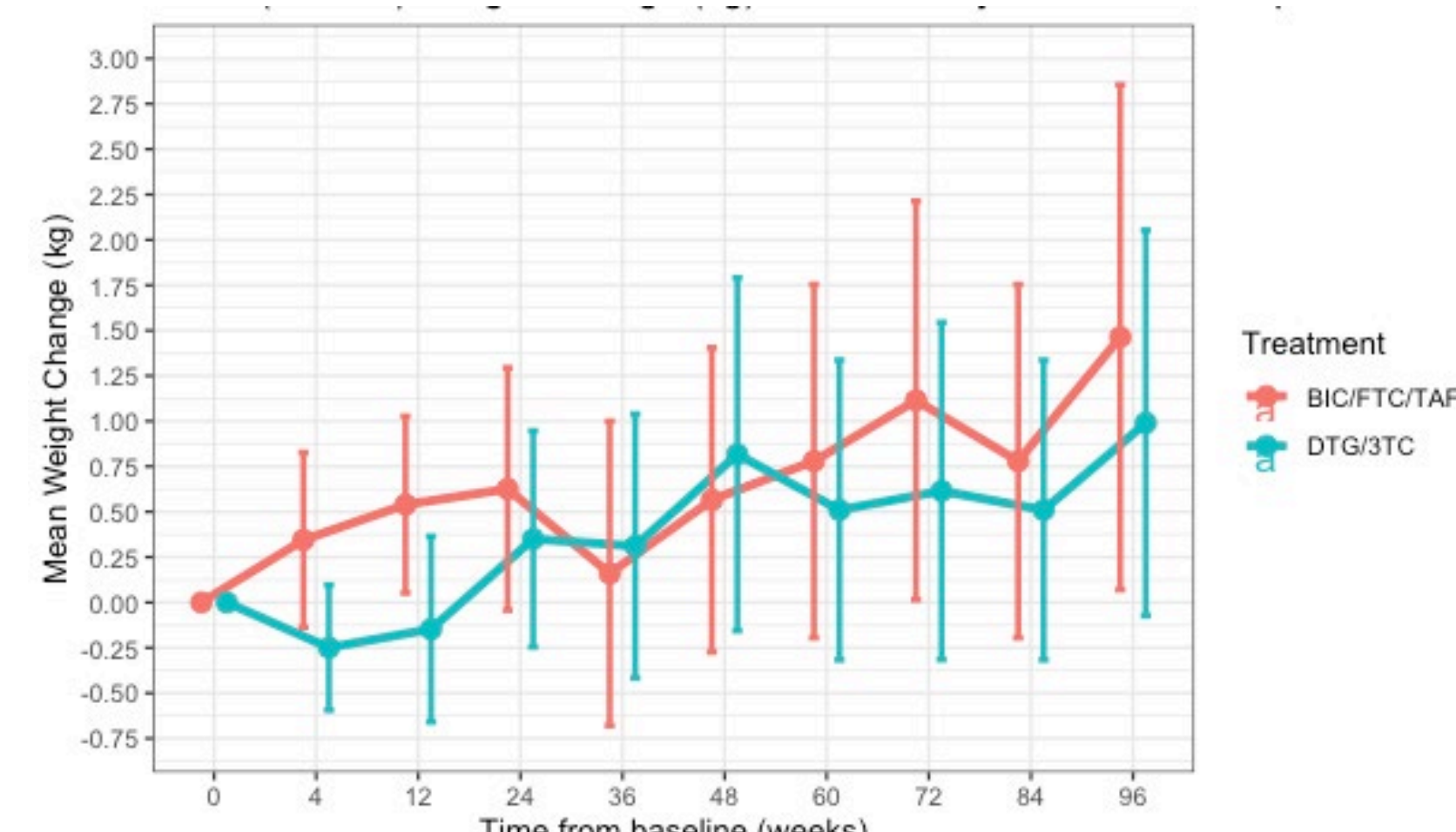
Table

	BIC/FTC/TAF	DTG/3TC
N	70.0 (49.6%)	71.0 (50.4%)
Socio-demographic factors		
Age, years (mean, SD)	45.6 (11.2)	44.7 (11.1)
Women (N, %)	11.0 (15.7%)	8.0 (11.3%)
Ethnicity (N, %)		
Caucasian	51.0 (72.9%)	59.0 (83.1%)
Latin	17.0 (24.3%)	12.0 (16.9%)
Afroamerican	2.0 (2.9%)	0.0 (0.0%)
HIV-associated Variables		
Risk factor for HIV acquisition		
Heterosexual	18.0 (25.7%)	13.0 (18.3%)
MSM	38.0 (54.3%)	44.0 (62.0%)
IDU	4.0 (5.7%)	4.0 (5.6%)
Unknown	7.0 (10.0%)	8.0 (11.3%)
Other	3.0 (4.3%)	2.0 (2.8%)
Previous AIDS (CDC) (N, %)	5.0 (7.1%)	11.0 (15.5%)
Nadir CD4, cells/uL, mean(SD)	352.2 (226.8)	383.7 (263.1)
Previous AIDS (CDC)	63.0 (90.0%)	63.0 (88.7%)
CD4 T-cells/uL (mean, SD)	786.8 (296.7)	792.8 (291.7)
CD8+ T-cells/uL (mean, SD)	774.3 (326.2)	888.4 (347.4)
CD4/CD8 ratio (mean, SD)	1.2 (0.6)	1.0 (0.5)
Years under VL suppression (mean, SD)	6.8 (5.8)	6.2 (4.2)
Comorbidities		
Infectious	48.0 (68.6%)	47.0 (66.2%)
Gastrointestinal	63.0 (27.4%)	52.0 (24.2%)
Neurologic	21.0 (9.1%)	26.0 (12.1%)
Cardiovascular	11.0 (4.8%)	10.0 (4.7%)
Respiratory	18.0 (7.8%)	16.0 (7.4%)
Metabolic	8.0 (3.5%)	11.0 (5.1%)
Renal	31.0 (13.5%)	26.0 (12.1%)
Hepatic	3.0 (1.3%)	5.0 (2.3%)
Other	5.0 (2.2%)	5.0 (2.3%)
Co-medications	70.0 (30.4%)	64.0 (29.8%)
Co-medications	31.0 (44.3%)	30.0 (42.3%)
Metabolic parameters		
Baseline weight, kg(mean, SD)	78.1 (13.8)	76.5 (14.3)
BMI, kg/m2 (mean, SD)	26.1 (4.4)	25.6 (4.5)
(mean, SD)	228.5 (1184.8)	101.3 (109.1)
Total Cholesterol, mg/dL (mean, SD)	186.8 (32.3)	187.5 (37.8)
HDL Cholesterol, mg/dL (mean, SD)	376.9 (1673.5)	103.2 (221.0)
LDL Cholesterol, mg/dL (mean, SD)	496.9 (1665.8)	217.2 (282.1)

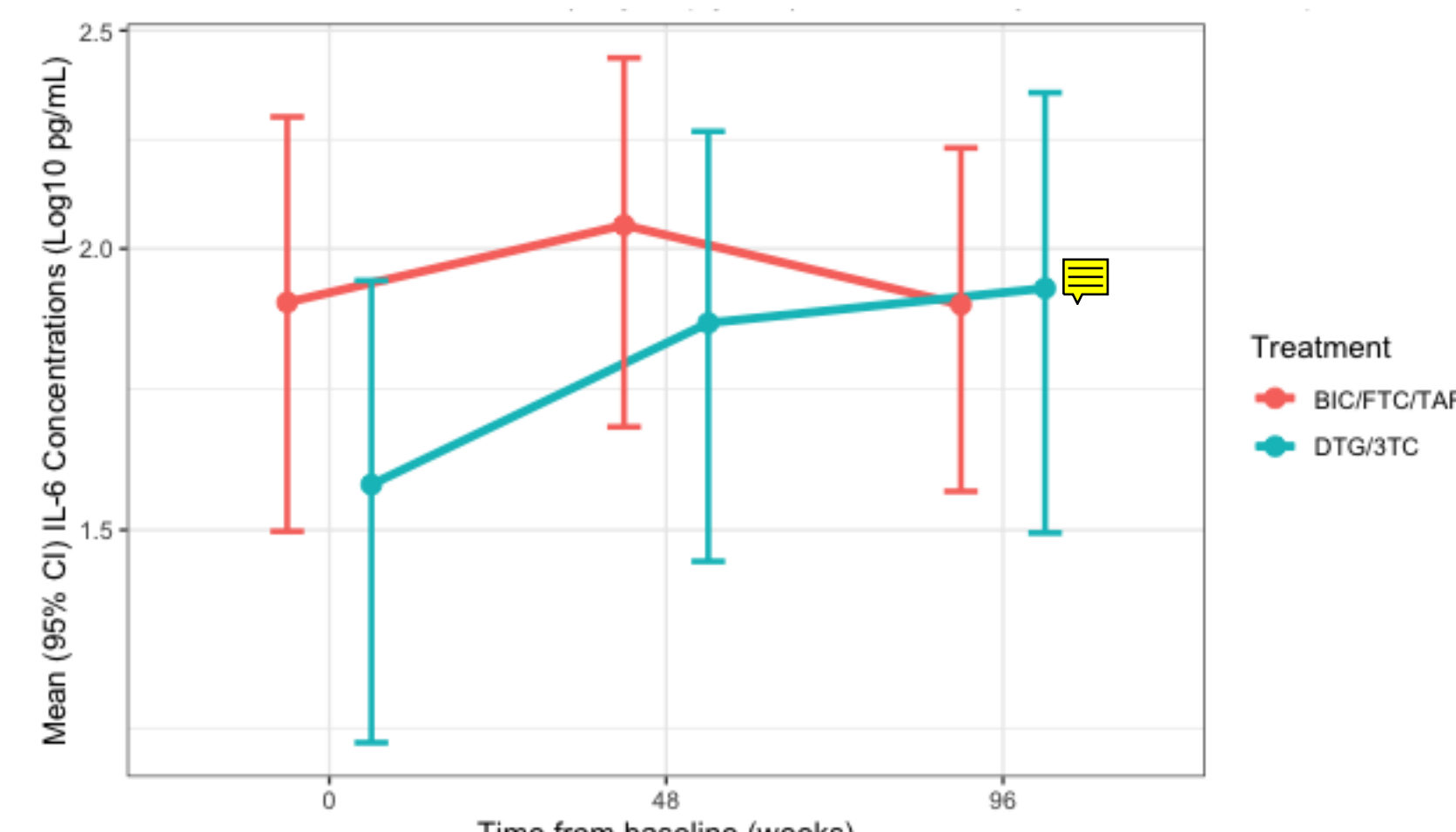
Virological Efficacy



Weight changes

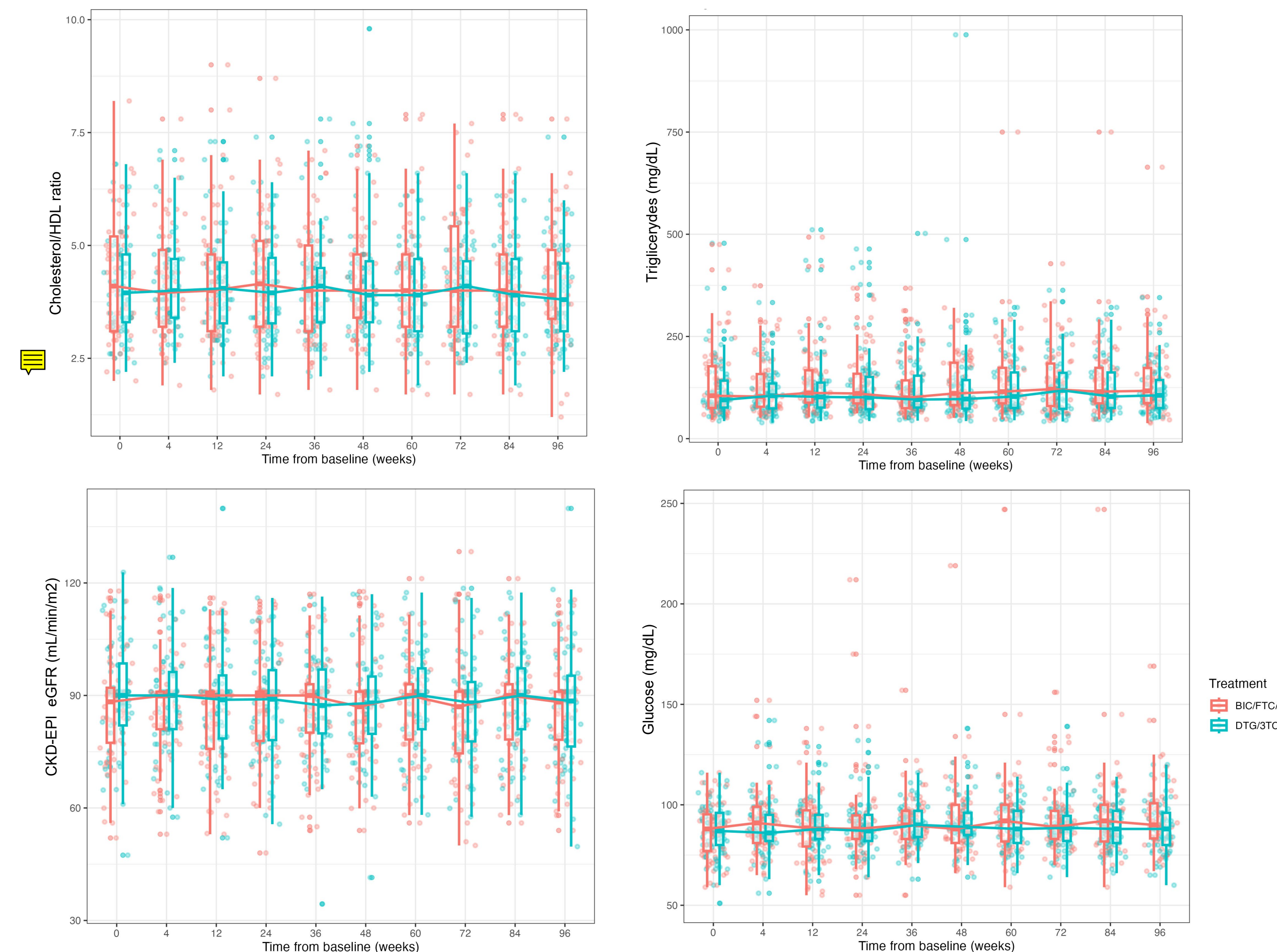


IL-6 Plasma Levels

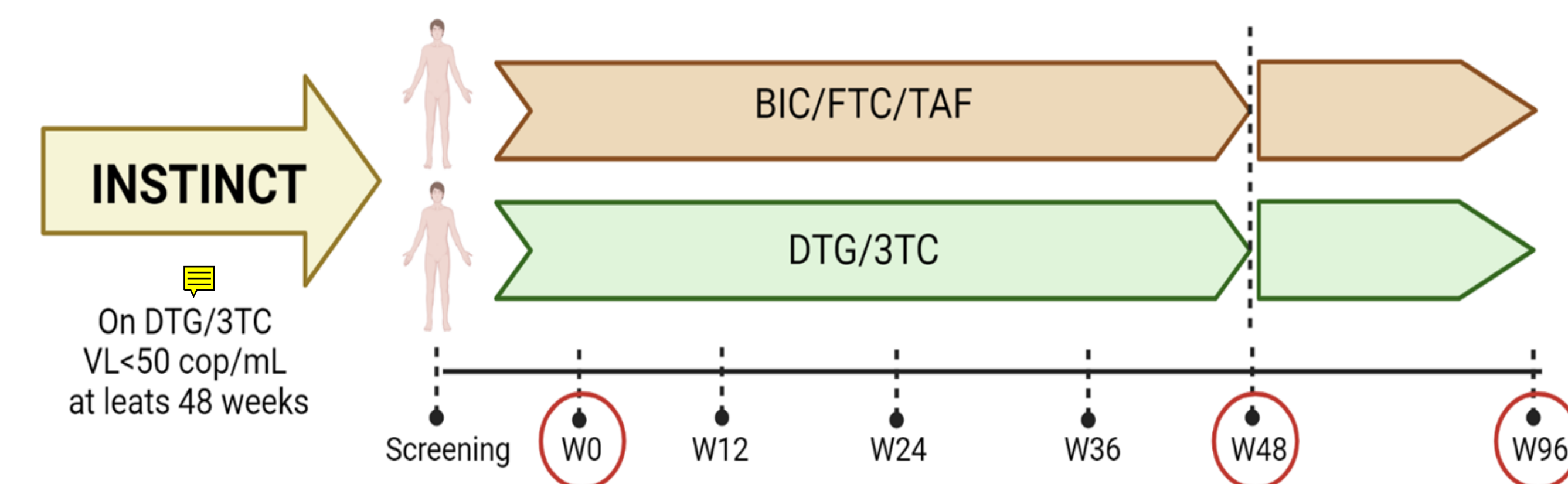
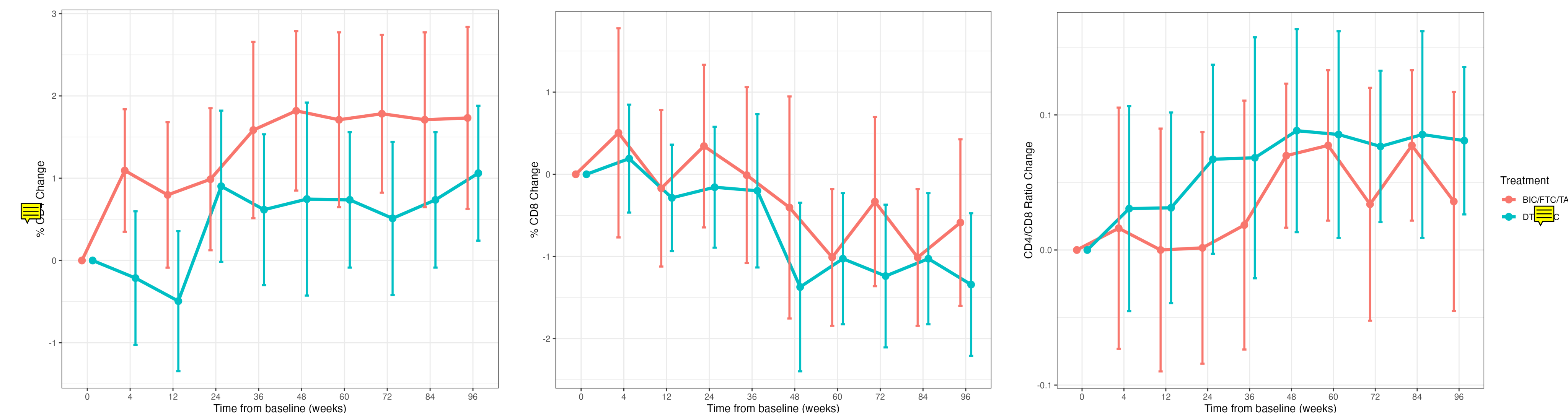


After 96 weeks from switching DTG/3TC to BIC/FTC/TAF we found no significant effects on weight, cholesterol levels, and systemic inflammation (IL-6).

Renal and Metabolic Parameters in Plasma



CD4 cells, CD8 cells and CD4/CD8 ratio



CONCLUSIONS

Switching from DTG/3TC to BIC/FTC/TAF in virologically suppressed individuals showed comparable effects on weight, cholesterol levels, and systemic inflammation (IL-6) compared to continuing DTG/3TC. Ongoing analyses of additional inflammatory markers are needed to determine if either regimen may lead to differential effects on systemic inflammation.

ADDITIONAL KEY INFORMATION

This study (ISR-17-10294) was funded by Gilead and monitored by Fundación GeSIDA. We would like to thanks to María Fons and Laura Luna for technical assistance.

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