

# STARTING ANTIRETROVIRAL THERAPY (ART) AT THE FIRST HIV-SPECIALIST APPOINTMENT WITH OR WITHOUT BASELINE LABORATORY DATA WITH BIC/FTC/TAF (THE BIFAST STUDY)

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## BACKGROUND:

Starting ART as soon as possible, even without baseline laboratory data, is highly recommended in resource poor settings, however its implementation in wealthy countries is controversial. We sought to evaluate the safety of this strategy in a referral HIV clinic in downtown Madrid.

## METHODS:

Phase IV, open-label, non-randomized, single-centre clinical trial. Patients referred to the HIV-clinic were offered same day ART with BIC/FTC/TAF whether or not having baseline laboratory data (Group 1, without lab data (WOLD); group 2 with lab data (WLD). Results of VL, CD4 and PRO at week 24 are shown here.

## RESULTS:

The main characteristics of 59 included subjects are described in Figure 1. Four patients (6.8%) were lost to follow-up (2 in each arm); one patient discontinued treatment because a suspected TB infection and four patients presented VL >50 cop/mL at week 24 (90, 68, 53, 53 cop/mL, respectively) (Figure 2). An improvement in subjects' self-perception (decrease of anxiety/depression symptoms and increase in happiness and optimistic perception about the future) was observed in PRO in both groups (Figures 3,4).

## CONCLUSIONS:

Starting ART at the first HIV-specialist appointment with BIC/FTC/TAF, with or without laboratory data, is a safe strategy and diminishes patient anxiety within the first weeks of treatment.

VARIABLE	VALUE		
	WITHOUT LAB bDATA (WOLD) (N=20)	WITH LAB bDATA (WLD) (N=39)	
Median age – years (IQR)	32 (26-39)	35 (30 - 42)	
Males – number (%)	19 (95%)	38 (97.4%)	
Ethnicity – number (%)			
European	14 (70%)	22 (56.4%)	
Latin-American	6 (30%)	17 (43.6%)	
Mechanism of HIV acquisition – number (%)			
MSM	17 (85%)	34 (87.2%)	
Other	3 (15%)		
Coinfections – number (%)			
HBsAg	0	1 (2.6%)	
Syphilis	1 (5%)	8 (20.5%)	
Resistance (mutations) –number(%)			
NNRTIs 4 (6.8%) E138A (2), V108I (1), K103N (1)		4	
NRTIs 1 (1.7%) M184V		1	
PIs 1 (1.7%) L90M	1		
CD4 – cells/mm <sup>3</sup> ; median (IQR)	454 (286 - 725)	404 (238 - 668)	
< 200 cells/mm <sup>3</sup> (%)	1 (5%)	7 (18.4%)	
HIV-1 RNA viral load – (%)			
> 100,000 copies/mL	3 (15%)	11 (28.2%)	
> 500,000 copies/mL	1 (5%)	2 (5.1%)	
Median time from diagnosis to start of ART; days (IQR)	16 (13-22)	28 (14-63)	(p = 0.031)
Other baseline characteristics			
High school degree		37 (62.7%)	
Had sex with different partners		37 (62.7%)	
Used dating apps always or almost always		23 (39%)	
Chemsex users		18 (30.5%)	
Condomless sex		21 (35.6%)	
Practiced sex since knowing the diagnosis		26 (44%)	
Changed sexual habits since knowing HIV status		10 (17%)	

Table 1. Main clinical characteristics of patients.

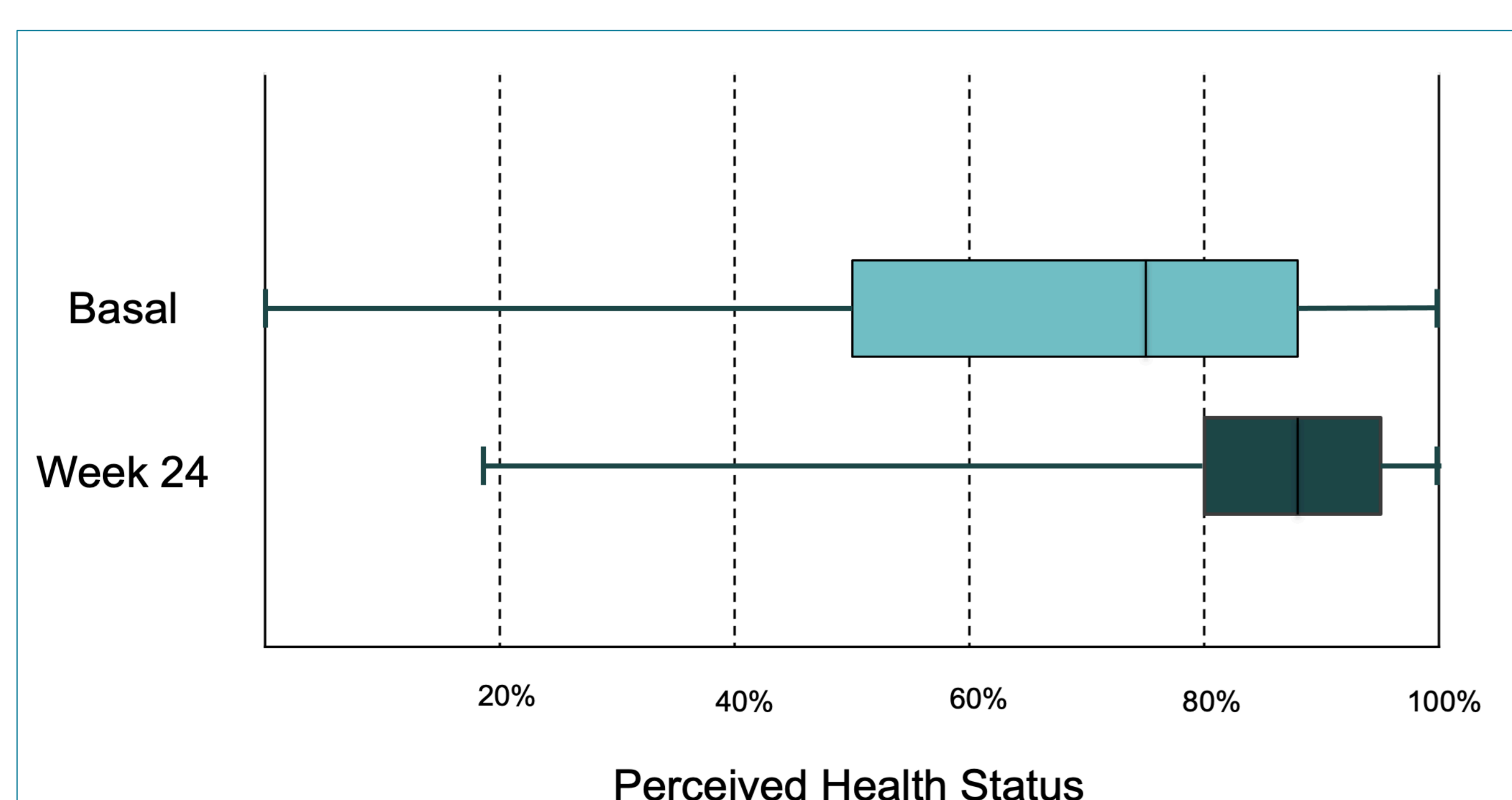


Figure 3. Perceived Health Status of both groups at baseline (n=59) and week 24 (n=55).

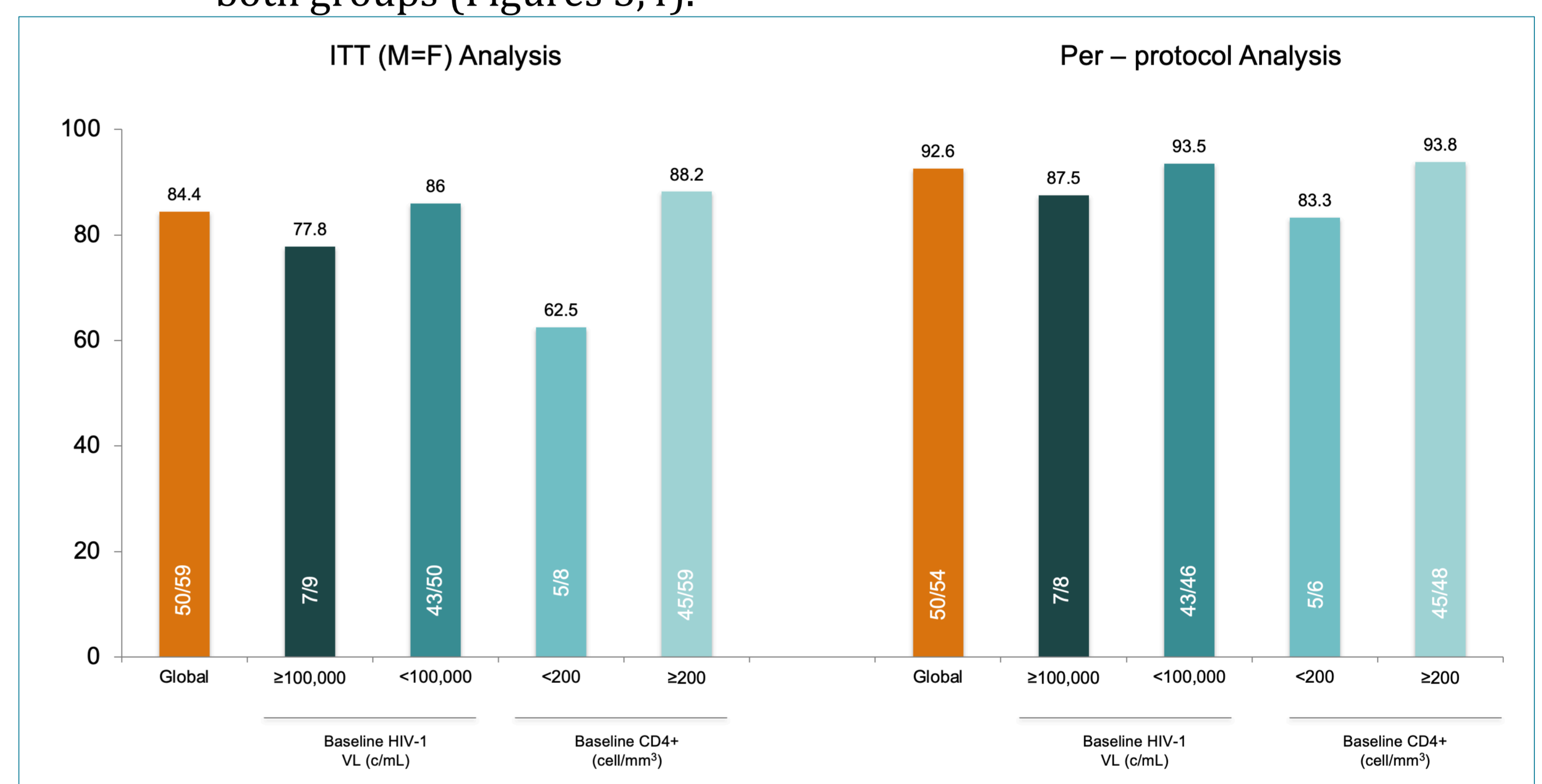


Figure 2. Global effectiveness of ART, both groups included.

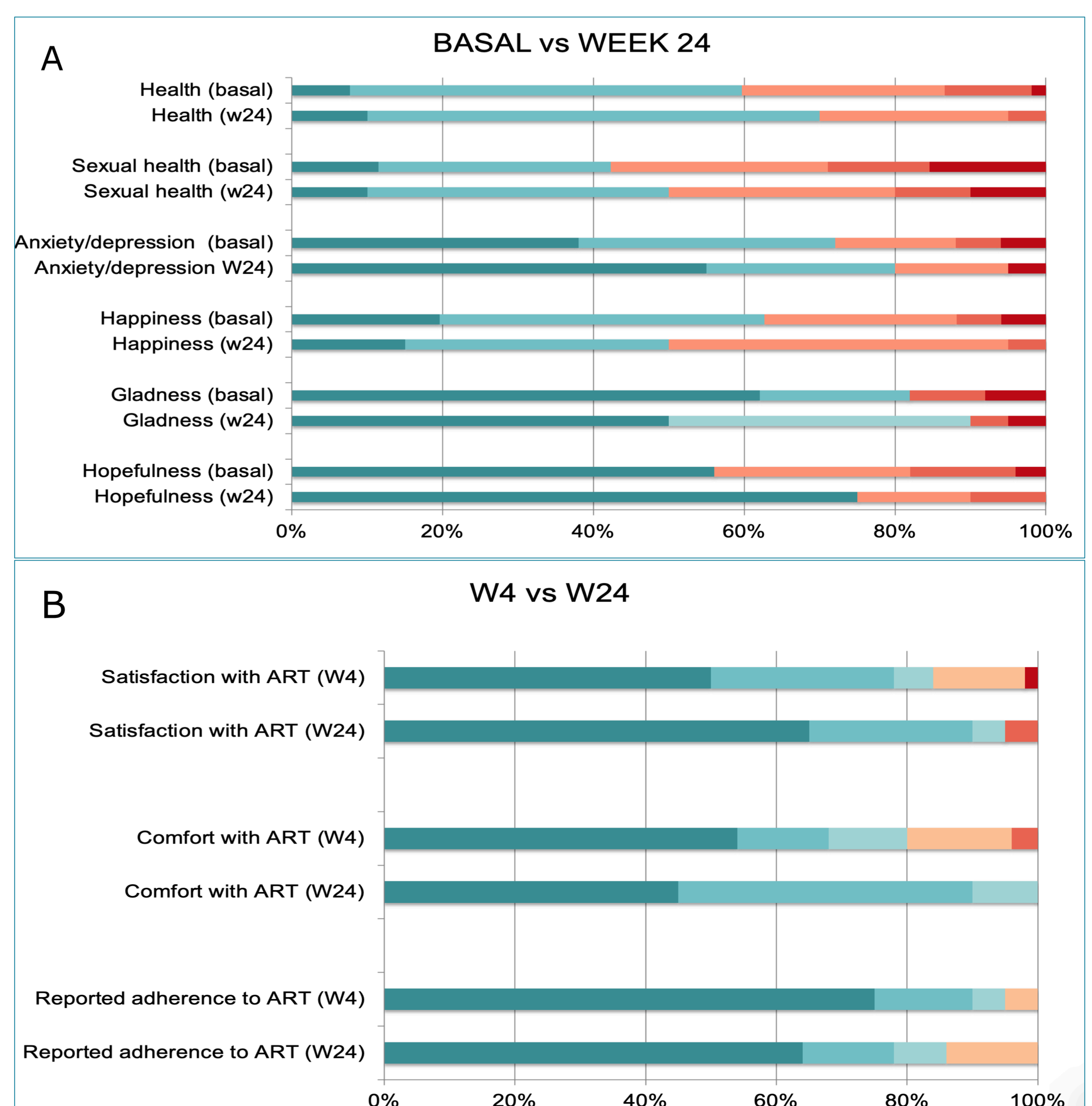


Figure 4. PRO of combined groups of treatment from baseline to week 24 (panel A) and of ART (panel B).