# 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.

VARIABLE   WITHOUT LAB BDATA (WOLD) (N=20) (N=20) (N=39)   Median age - years (IQR)   32 (26-39)   35 (30 - 42)   Males - number (%)   19 (95%)   38 (97.4%)					
(WOLD) (N=39)	<u>VARIABLE</u>		<u>VALUE</u>		
## Males - number (%)			(WOLD)	(WLD)	
Ethnicity – number (%)	Median age – years (IQR)		32 (26-39)	35 (30 - 42)	
European	Males – number (%)		19 (95%)	38 (97.4%)	
European 14 (70%) 22 (56.4%)  Latin-American 6 (30%) 17 (43.6%)  Mechanism of HTV acquisition – number (%)  MSM 17 (85%) 34 (87.2%)  Other 3 (15%)  Coinfections – number (%)  HBsAg 0 1 (2.6%)  Syphills 1 (5%) 8 (20.5%)  Resistance (mutations) – number (%)  NNRT15 4 (6.8%) 8 (20.5%)  Resistance (mutations) – number (%)  NNRT15 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Ethnicity	– number (%)			
Mechanism of HIV acquisition - number (%)   MSM   17 (85%)   34 (87.2%)			14 (70%)	22 (56.4%)	
NSM	Latin	-American	6 (30%)	17 (43.6%)	
Other					
Coinfections - number (%)		MSM	17 (85%)	34 (87.2%)	
HBsAg		Other	3 (15%)		
Syphilis	Coinfection	s – number (%)			
Resistance (mutations) -number(%)  NNRTIS 4(6.8%) 1					
NNRTIS   4(6.8%)   E138A (2), V108I (1), K103N (1)	S	yphilis	1 (5%)	8 (20.5%)	
NNRTIS   4(6.8%)   E138A (2), V108I (1), K103N (1)   4   4   4(6.8%)   NRTIS 1   (1.7%)   L90M   1   1					
### ### ##############################		cations) -number(%)			
CD4 - cells/mm³; median (IQR)   454 (286 - 725)   404 (238 - 668)	4(6.8%)	E138A (2), V108I (1), K103N (1)		4	
CD4 - cells/mm³; median (IQR)   454 (286 - 725)   404 (238 - 668)     < 200 cells/mm³ (%)   1 (5%)   7 (18.4%)     HIV-1 RNA viral load - (%)   3 (15%)   11 (28.2%)     > 100,000 copies/mL   1 (5%)   2 (5.1%)     Median time from diagnosis to star 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   10 (17%)		M184V		1	
< 200 cells/mm³ (%)       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 star 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         Chemsex users       18 (30.5%)         Condomless sex       21 (35.6 %)         Practiced sex since knowing the diagnosis         Changed sexual habits since knowing			1		
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 star of ART; days (IQR)  Other baseline characteristics  High school degree  Had sex with different partners  Used dating apps always or almost always  Chemsex users  Condomless sex  Practiced sex since knowing the diagnosis  Changed sexual habits since knowing					
> 100,000 copies/mL 3 (15%) 11 (28.2%) > 500,000 copies/mL 1 (5%) 2 (5.1%)  Median time from diagnosis to star 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 Chemsex users 18 (30.5%) Condomless sex 21 (35.6 %) Practiced sex since knowing the diagnosis Changed sexual habits since knowing	< 200 ce	ells/mm³ (%)	1 (5%)	7 (18.4%)	
> 500,000 copies/mL 1 (5%) 2 (5.1%)  Median time from diagnosis to star 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 Chemsex users 23 (39%) Condomless sex 21 (35.6 %) Practiced sex since knowing the diagnosis Changed sexual habits since knowing	HIV-1 RNA viral load – (%)				
Median time from diagnosis to star of ART; days (IQR)  Other baseline characteristics  High school degree  Had sex with different partners  Used dating apps always or almost always  Chemsex users  Condomless sex  Practiced sex since knowing the diagnosis  Changed sexual habits since knowing	> 100,000 copies/mL		3 (15%)	11 (28.2%)	
Other baseline characteristics High school degree Had sex with different partners Used dating apps always or almost always Chemsex users Condomless sex Practiced sex since knowing the diagnosis Changed sexual habits since knowing	> 500,0	00 copies/mL	1 (5%)	2 (5.1%)	
High school degree 37 (62.7%)  Had sex with different partners 37 (62.7%)  Used dating apps always or almost always  Chemsex users 18 (30.5%)  Condomless sex 21 (35.6 %)  Practiced sex since knowing the diagnosis  Changed sexual habits since knowing			16 (13-22)	28 (14-63)	(p =
High school degree 37 (62.7%) Had sex with different partners 37 (62.7%) Used dating apps always or almost always Chemsex users 18 (30.5%) Condomless sex 21 (35.6 %) Practiced sex since knowing the diagnosis Changed sexual habits since knowing	ARI;	days (IQR)	10 (13 22)	20 (11 00)	0.031)
Had sex with different partners  Used dating apps always or almost always  Chemsex users  Condomless sex  Practiced sex since knowing the diagnosis  Changed sexual habits since knowing	ARI;	days (IQR)	10 (10 22)	20 (11 00)	0.031)
Used dating apps always or almost always  Chemsex users  Condomless sex  Practiced sex since knowing the diagnosis  Changed sexual habits since knowing				20 (11 00)	0.031)
Chemsex users  Condomless sex  Condomless sex  Practiced sex since knowing the diagnosis  Changed sexual habits since knowing  10 (17%)	Other baseli	ne characteristics			0.031)
Condomless sex  Practiced sex since knowing the diagnosis  Changed sexual habits since knowing  10 (17%)	Other baseli High so Had sex with	ne characteristics chool degree different partners		37 (62.7%)	0.031)
Practiced sex since knowing the diagnosis  Changed sexual habits since knowing  10 (17%)	Other baseli High so Had sex with Used dating ap	ne characteristics chool degree different partners ps always or almost		37 (62.7%) 37 (62.7%) 23 (39%)	0.031)
diagnosis  Changed sexual habits since knowing  10 (17%)	Other baseli High so Had sex with Used dating ap a Chem	ne characteristics chool degree different partners ps always or almost lways nsex users		37 (62.7%) 37 (62.7%) 23 (39%) 18 (30.5%)	0.031)
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Table 1. Main clinical characteristics of patients.

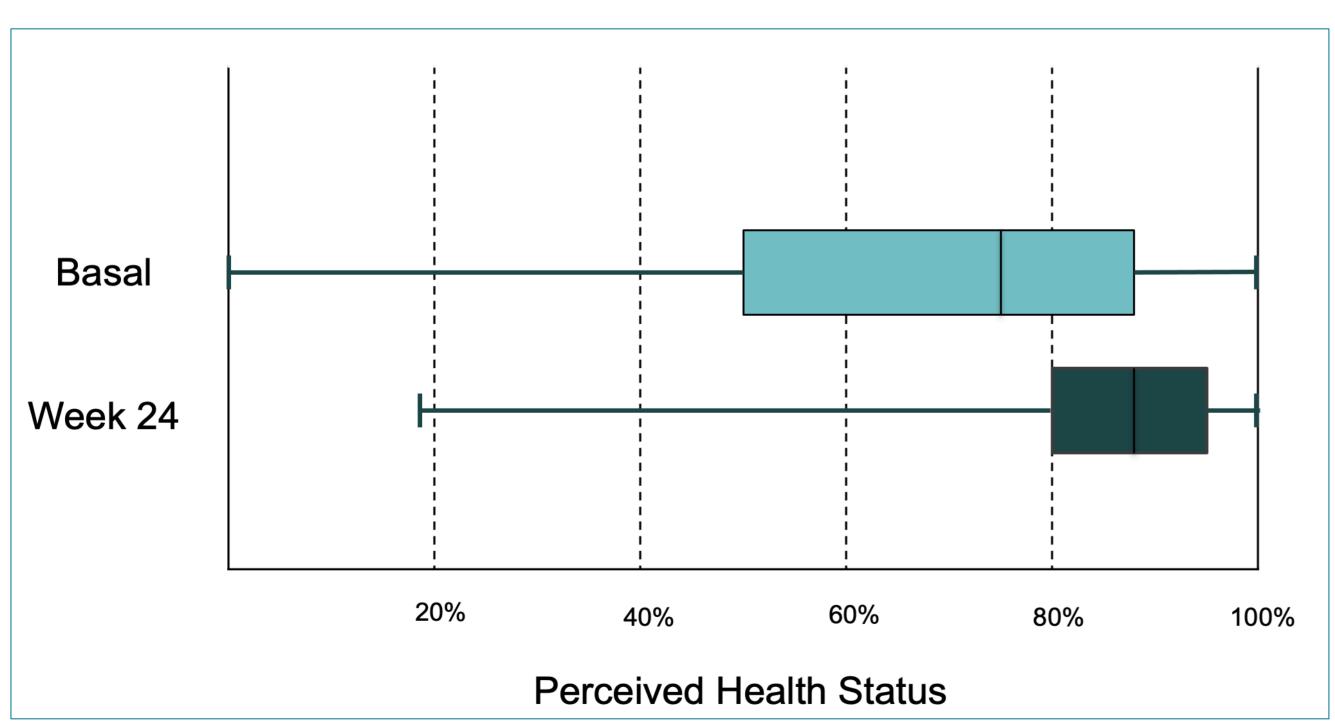


Figure 3. Perceived Health Status of both groups at baseline (n=59) and week 24 (n=55).

### **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' selfperception (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.

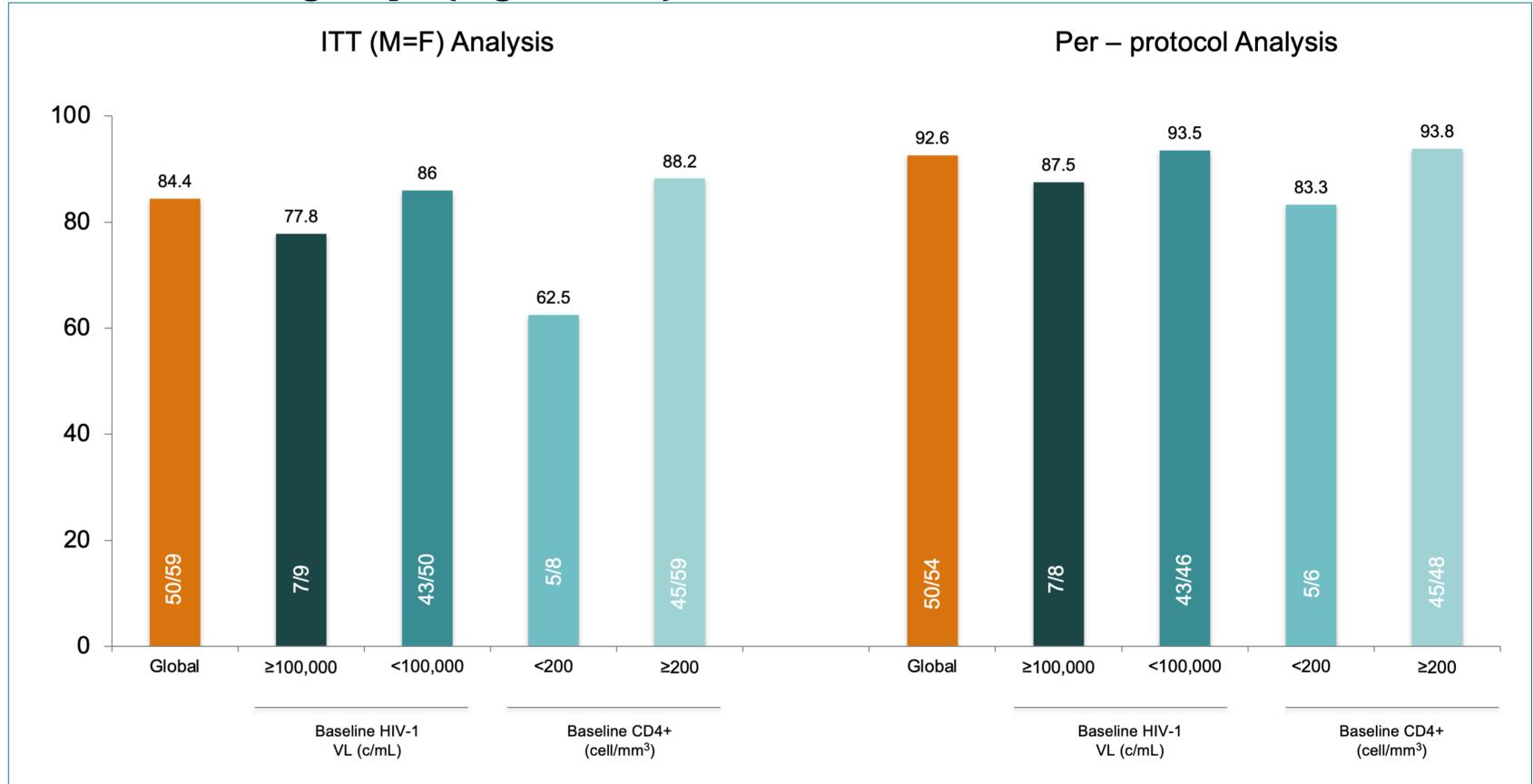


Figure 2. Global effectiveness of ART, both groups included.

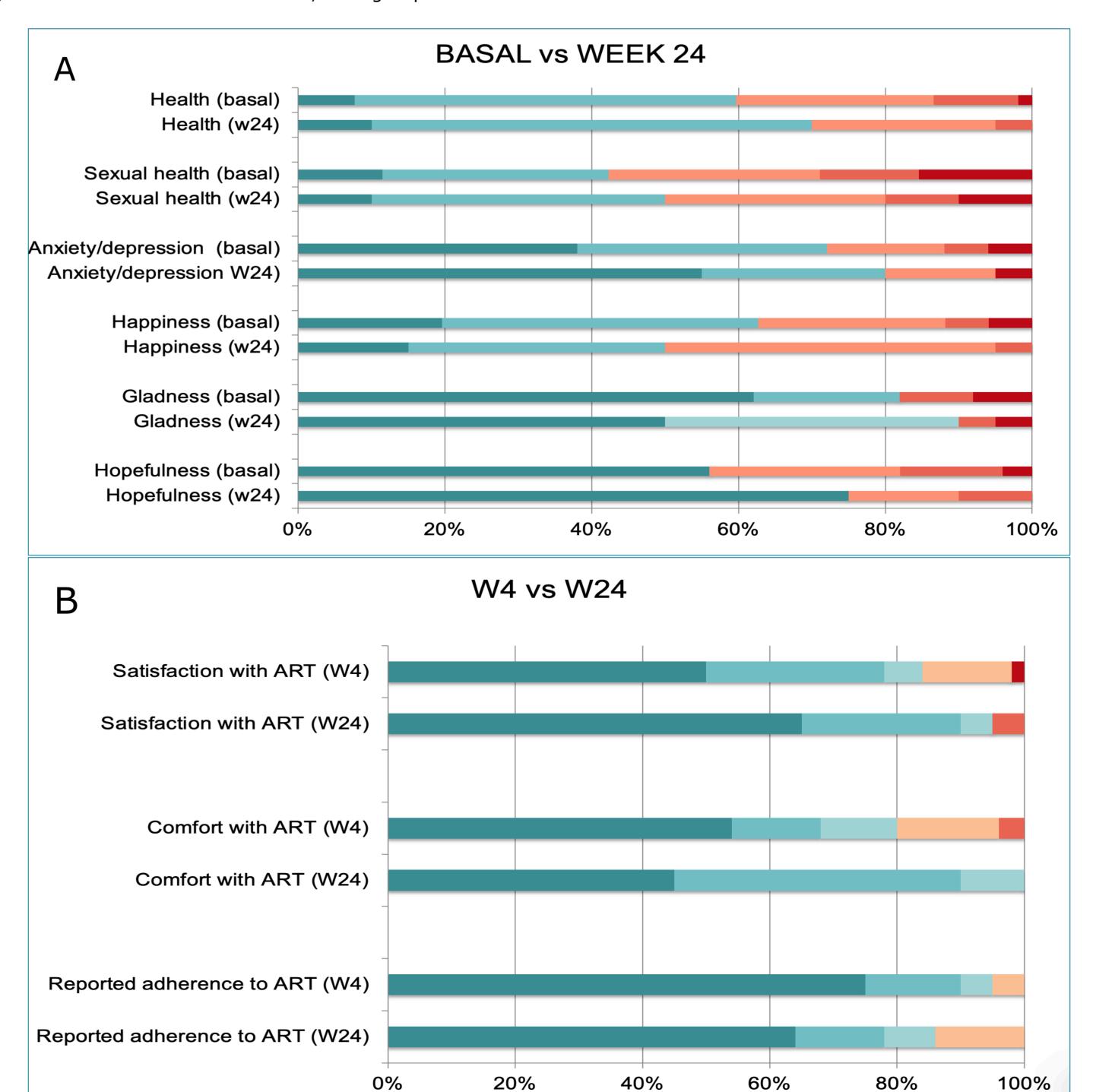


Figure 4. PRO of combined groups of treatment from baseline to week 24 (panel A) and of ART (panel B).



