

TDF-FTC versus Placebo as HIV PrEP for Transgender Women
iPrEx Trial Substudy

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iPrEx Substudy: Study Design

- **Background:** Subgroup analysis of the iPrEX randomized controlled trial (RCT) and open-label extension (OLE), designed to assess efficacy, tolerability, drug concentrations, and adherence with TDF-FTC PrEP for transgender women
- **Participants from the RCT (all assigned male sex at birth)**
 - Total number = 339
 - 296 who identified as "trans"
 - 29 who identified as women
 - 14 who identified as men but reported taking feminizing hormone therapy
- **Participants in OLE (all assigned male sex at birth)**
 - 192 transgender women enrolled
 - 151 (79%) chose to take PrEP for at least part of the study

Outcomes:

- HIV seroconversions
- Drug concentrations overall and at the time of seroconversion

TDF-FTC versus Placebo as HIV PrEP for Transgender Women (TGW) iPrEx Substudy: Baseline Demographics in the RCT

Variable	Value	TGW (n = 339)	MSM (n = 2,160)
Mean age	Years	26.2	27.3
Education	Less than High school	126 (37%)	397 (19%)
	High school	169 (50%)	1,209 (57%)
	College	42 (13%)	527 (25%)
Partners (baseline)	≤1	14 (4%)	198 (9%)
	1-5	82 (24%)	803 (37%)
	5-10	50 (15%)	476 (22%)
	>10	193 (57%)	683 (32%)
Condomless RAI	No	49 (14%)	965 (45%)
	Yes	290 (86%)	1,195 (55%)
Cocaine or meth use	No	302 (89%)	2,020 (94%)
	Yes	37 (11%)	140 (7%)

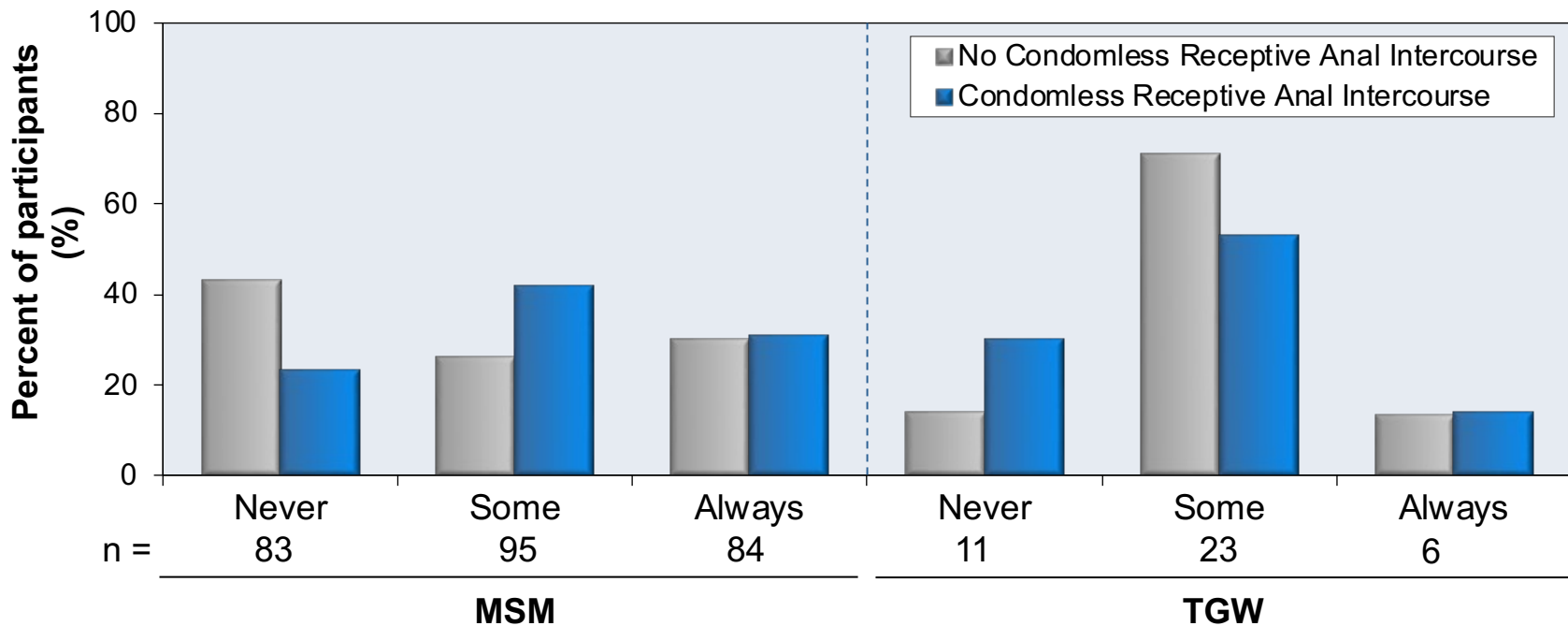
Abbreviations: RAI = receptive anal intercourse

TDF-FTC versus Placebo as HIV PrEP for Transgender Women (TGW) iPrEx Substudy: Baseline Demographics in the RCT (continued)

Variable	Value	TGW (n = 339)	MSM (n = 2,160)
STI (past 6 months)	No	212 (63%)	1,635 (76%)
	Yes	127 (38%)	525 (24%)
Circumcised	No	323 (96%)	1,835 (85%)
	Yes	13 (4%)	320 (15%)
Living situation	With partner	27 (8%)	154 (7%)
	Alone	77 (23%)	306 (14%)
	With family/friends	230 (68%)	1,663 (77%)
	Other	5 (2%)	37 (2%)
Transactional sex	No	122 (36%)	1,250 (63%)
	Yes	217 (64%)	810 (38%)

TDF-FTC versus Placebo as HIV PrEP for Transgender Women (TGW) iPrEx Substudy: Results from the RCT

Proportion of participants by consistency of drug detection (never, some, always), gender, and non-condom receptive anal intercourse (ncRAI), regardless of hormone use



TDF-FTC versus Placebo as HIV PrEP for Transgender Women (TGW) iPrEx Substudy: Results (Drug Concentrations & HIV Incidence in the OLE)

Drug level by dried blood spot	Gender	Person years of follow up	HIV acquisitions (number)	HIV acquisition (Rate) per 100 person years follow up
Off PrEP	MSM	447	12	2.68
	TGW	53	1	1.90
Below limit of quantification	MSM	326	17	5.21
	TGW	58	1	1.72
<2 pills/week	MSM	324	8	2.47
	TGW	76	1	1.31
2-3 pills/week	MSM	156	1	0.64
	TGW	24	0	0.00
4-6 pills/week	MSM	288	0	0.00
	TGW	28	0	0.00
Daily	MSM	176	0	0.00
	TGW	5	0	0.00

Source: Deutsch MB, et al. Lancet HIV. 2015;2:e512-9.

TDF-FTC versus Placebo as HIV PrEP for Transgender Women (TGW) iPrEx Substudy: Interpretation

Interpretation: “There were no HIV infections among TGW having drug concentrations commensurate with use of 4 or more FTC/TDF tablets per week. TGW receiving PrEP had low drug concentrations, especially at times of potential HIV exposure, leading to no PrEP effectiveness among this subgroup.”