

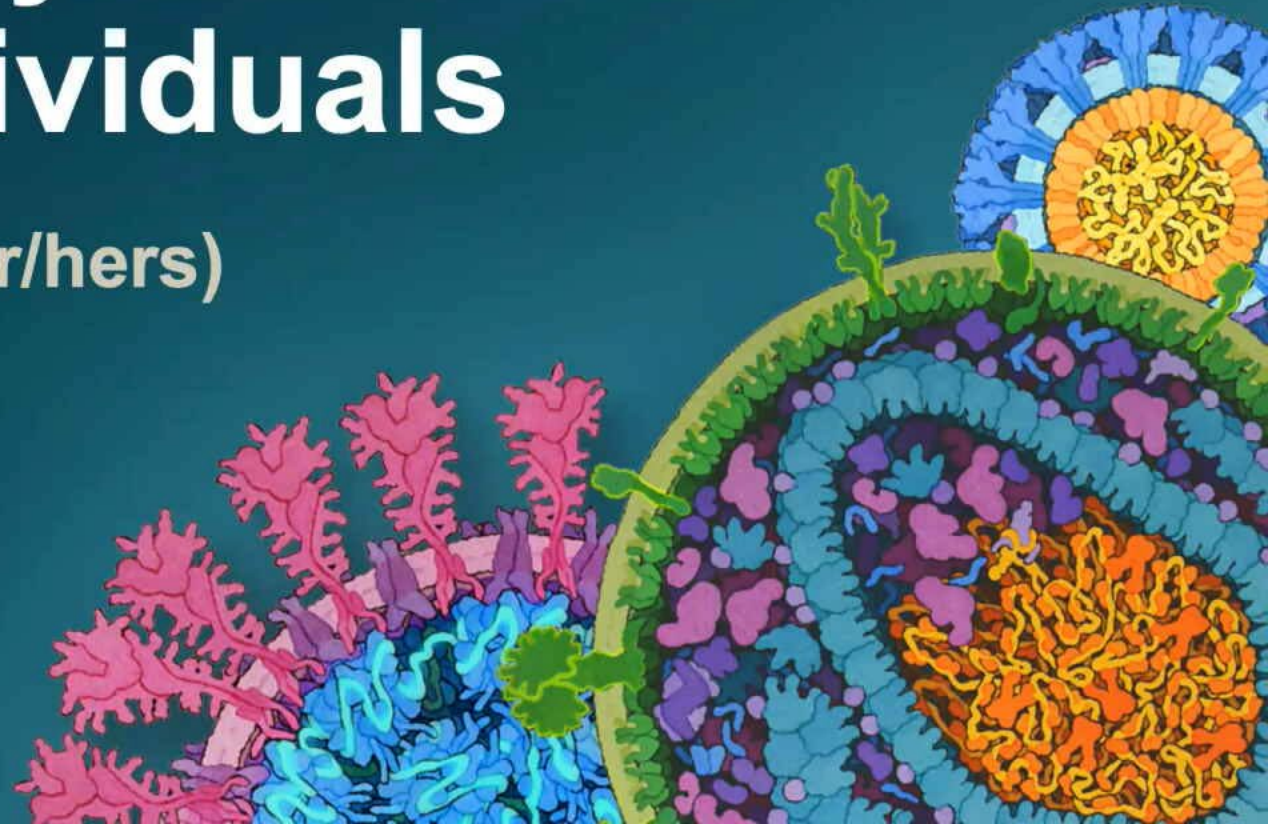


# The Bi-directional Effects of Hormone Therapy and PrEP in Transgender Individuals

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# Background

- Drug-drug interactions not expected between gender-affirming hormone therapy (HT) and preexposure prophylaxis (PrEP) due to different metabolic pathways
- The bi-directional effect of HT and PrEP concentrations among transgender (TG) individuals have been examined
  - Mixed results
  - Evaluation periods short
  - Small cohorts, few transgender men
- Outcome of interest: bi-directional effects of HT and tenofovir disoproxil fumarate/ emtricitabine (TDF/FTC) concentrations in a large cohort of TG individuals over 3 months

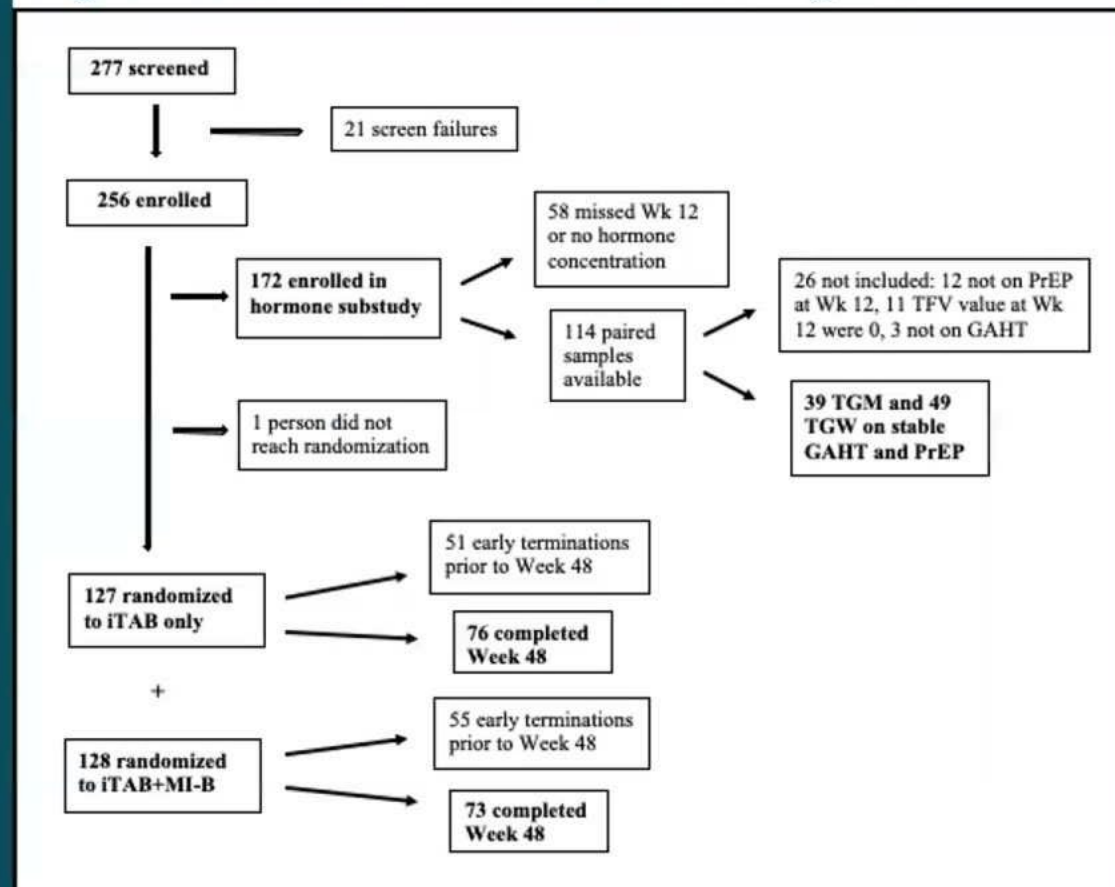




# Methods

- iTAB plus Motivational Interviewing for PrEP Adherence in Transgender Individuals (ImPrEPT) study: RCT of 256 TG individuals, using iTAB with and without brief motivational interviewing over 48 weeks (**Morris, Poster 990**)
- Individuals enrolled in hormone sub-study (n=172)
  - Tenofovir diphosphate (TFV-DP) in dried blood spots (DBS) and serum sex hormones at weeks 0 and 12
  - Desired hormone effects and satisfaction with HT measured at weeks 0 and 24

Figure 1: ImPrEPT Consort Flow Diagram





# Statistical Analysis

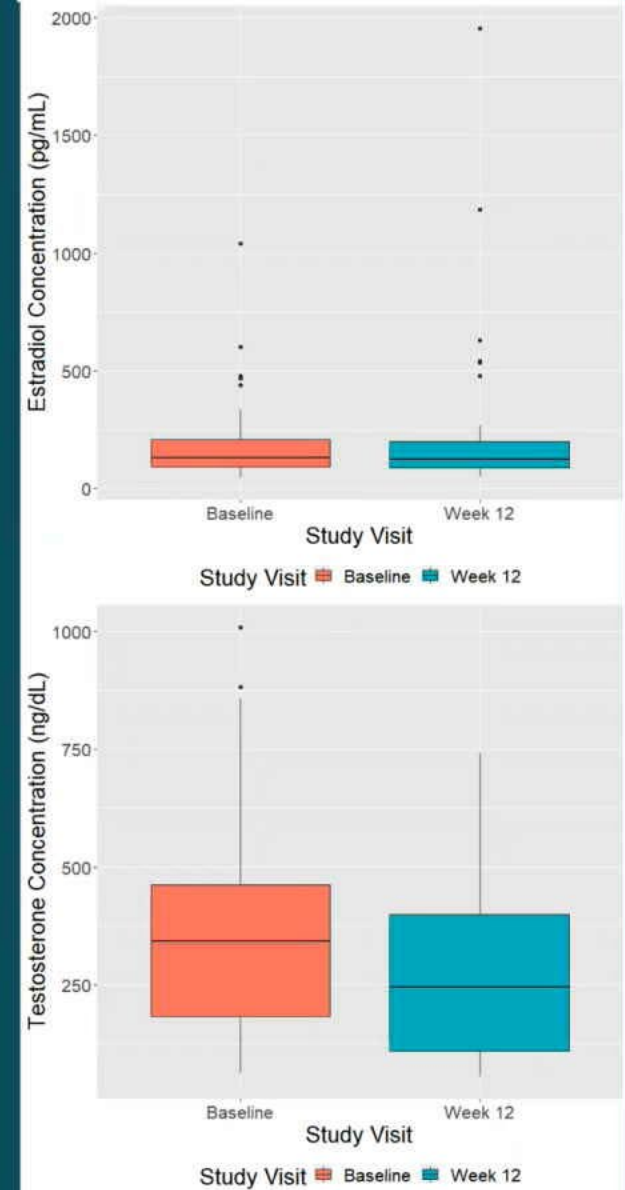
- TG women and non-binary individuals assigned male at birth = transgender women (TGW)
- TG men and non-binary individuals assigned female at birth = transgender men (TGM)
  - Included if on stable estrogen or testosterone-containing regimens
  - Removed if reported not taking PrEP or TVF-DP concentration undetectable
- Wilcoxon statistical tests and linear regression adjusting for confounding factors (Creatinine clearance, weight, BMI)
  - Changes in HT concentrations from week 0 to 12
  - Difference in TFV-DP concentrations in TG taking and not taking HT at week 12
  - Changes in satisfaction with HT gender-affirming traits from week 0 to 24
- Cohen's d used to measure effect size of hormone concentrations



# Results: Hormone Concentrations

- N=114; mean age 32.7y (SD 9.6); 14% Black, 44% White, 31% Latinx
- 49 TGW on stable estrogen, estradiol concentrations did not change significantly between Weeks 0 and 12 in those taking PrEP (185.2 vs 221.8 pg/mL,  $p=0.53$ ).
  - Cohen's d: -0.09116937 (very small)
- 39 TGM on stable testosterone, testosterone concentrations were lower between Weeks 0 and 12 in individuals taking PrEP (373.2 vs 274.3 ng/dL,  $p=0.052$ ).
  - Cohen's d: 0.4639996 (small)

Figure 2: Box plots of hormone concentrations before and after TDF/FTC PrEP dosing.





# Results: PrEP Concentrations and HT Satisfaction

**Table 1. PrEP Drug Concentrations and Satisfaction Scores by Gender Identity**

	Transgender Women (n=112)	p-value	Transgender Men (n=60)	p-value
<b>Week 12 TFV-DP Concentration, fmol/punch (SD)*</b>		0.26		0.49
<b>No hormone therapy</b>	1885.8 (1058.7) (n=28)		1682.0 (791.6) (n=10)	
<b>Yes hormone therapy</b>	1589.5 (819.1) (n=67)		1961.6 (966.4) (n=39)	
<b>Body Image Satisfaction (SD)**</b>		0.83		0.20
<b>Week 0</b>	2.7 (0.80) (n=23)		2.2 (0.60) (n=10)	
<b>Week 24</b>	2.6 (0.91) (n=19)		1.9 (0.62) (n=9)	
<b>Satisfaction with HT on gender transition (SD)***</b>		0.35		1.0
<b>Week 0</b>	1.9 (1.04) (n=23)		1.6 (0.70) (n=10)	
<b>Week 24</b>	1.9 (0.89) (n=19)		1.7 (0.87) (n=9)	

TFV-DP= tenofovir-diphosphate; SD= standard deviation; HT= hormone therapy

\*Adjusting for confounding factors age, creatinine clearance and weight.

\*\*Body Image Satisfaction summed 5 questions about desired physical effects from HT (low body image is 1, high body image is 5)

\*\*\*Satisfaction with HT on gender transition is based on question "how satisfied are you with your HT on your gender transition?" (low satisfaction score is 1, high satisfaction score is 5)





# Discussion

- Transgender individuals both taking and not taking HT had similar TFV-DP concentrations in DBS after 12 weeks of daily reported TDF/FTC PrEP use
- Serum estradiol concentrations not affected by TDF/FTC
- Serum testosterone concentrations were marginally lower in TGM taking TDF/FTC; however, change is unlikely clinically meaningful
- No change in the perceived effects of HT in those taking PrEP



## Limitations and Strengths

- Limitations
  - Attrition over time
  - Not a true PK study
  - Random hormone measurements
- Strengths
  - Large and diverse study population
  - 3-month follow up
  - Evaluation of perceived impact of PrEP on HT results

## Conclusion and Future Directions

- No clinically meaningful bi-directional effects between PrEP with TDF/FTC and gender-affirming HT concentrations
- Future directions include examining effects between PrEP with TAF/FTC and HT concentrations



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