



# **Peer Delivered HIV Self-Testing, STI Self-Sampling and PrEP for Transgender Women in Uganda: A Randomized Trial**

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# Background

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- Transgender women (TGW) are **14 times** as likely to have HIV as adults in the general population<sup>1</sup>.
- TGW have higher prevalence of rectal sexually transmitted infections (STI) than men who engage in sex with other men<sup>2</sup>.
- The World Health Organization recommends peer support, HIV self-testing (HIVST) and STI self-sampling (STISS) as additional approaches for delivering HIV/STI testing services<sup>3</sup>.



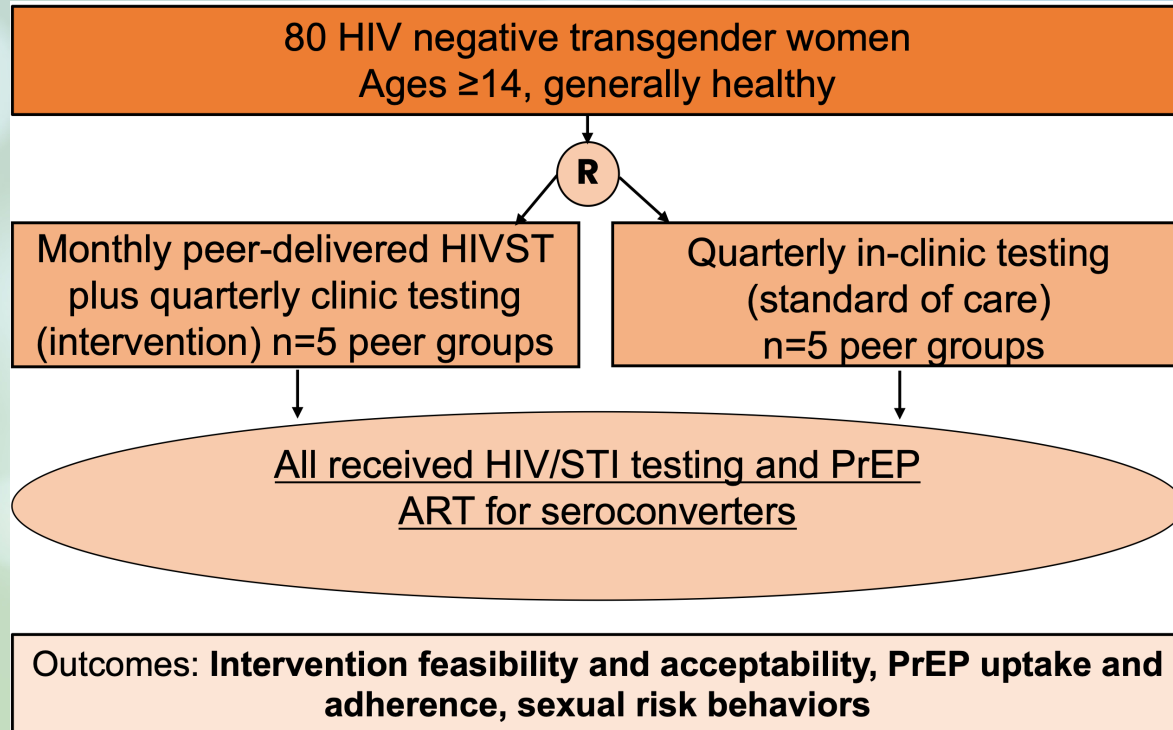


# Rationale

- Peer-delivered HIVST and STISS could facilitate oral pre-exposure prophylaxis (PrEP) adherence among TGW, but no studies in sub-Saharan Africa have evaluated this strategy.
- We conducted a randomized trial to test if peer-delivered combination prevention (HIVST, STISS and PrEP) increased testing uptake and empowered effective prevention decision making among HIV-negative TGW initiating PrEP in Uganda.

# Peer Cluster RCT Design

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## Study Procedures

### Control

(n=5 peer groups)

- PrEP initiation in clinic
- Quarterly HIV/STI testing
- Quarterly PrEP refills
- Urine tenofovir testing with drug level feedback for adherence counseling
- STI diagnosis and treatment
- Risk reduction counseling
- Condom provision

### Intervention

(n=5 peer groups)

Control arm services plus:

- Monthly peer delivery of HIVST and STISS
- Monthly PrEP refills in between quarterly clinic visits
- Peer adherence support
- Peer assisted partner notification and linkage to care



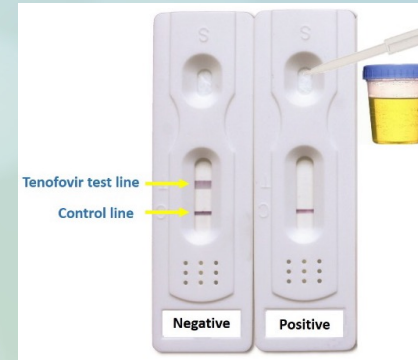
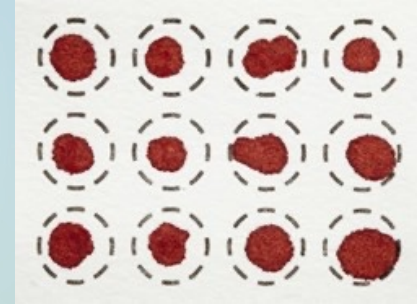
Intent to treat comparison by randomization arm





# Adherence Measurement

- 1) Tenofovir diphosphate levels (TFV-DP) in dried blood spot samples (DBS)
- 2) Urine tenofovir testing with real-time drug level feedback to support adherence counseling





# Trial Outcomes

## Primary outcomes

- 1) Acceptability of peer-delivered HIVST, STISS, PrEP
- 2) Feasibility of peer delivery
- 3) Oral PrEP adherence measured using:
  - a) TFV-DP  $\geq 700$  fmol per punch
  - b) Urine tenofovir  $\geq 1,500$  ng/ml

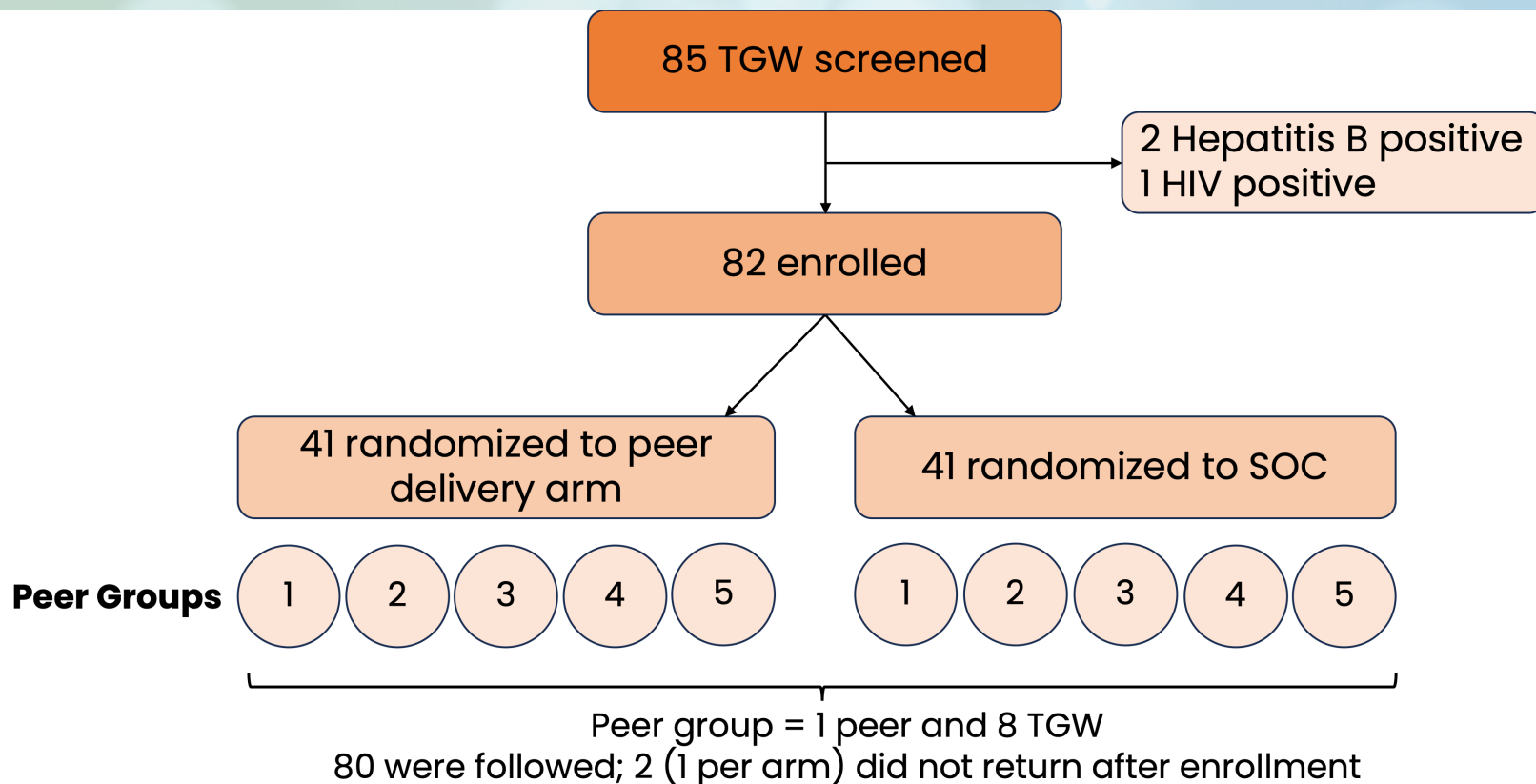
## Secondary outcomes

- 1) Condomless sex
- 2) CT/NG incidence

PrEP adherence and condomless sex compared by arm using generalized estimating equation models

# Trial Profile

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Baseline Characteristics	Peer Delivery (N=41) N (%) or Median (IQR)	SOC (N=41) N (%) or Median (IQR)
Age, years (median, IQR)	22 (20–24)	21 (20–23)
Education (years)	11 (9–13)	11 (10–13)
≤10	15 (37)	12 (29)
>10	26 (63)	29 (71)
Monthly income (UGX; median, IQR)	250,000 (150,000–330,000)	200,000 (200,000–300,000)
Partnership status		
Intimate partner	25 (61)	19 (49)
No intimate partner	16 (39)	22 (54)
Age at onset of sex work (years)	19 (17–19)	18 (17–19)
Sex work main source of income (n=62)		
Yes	15 (52)	16 (48)
No	14 (48)	17 (52)
Sex acts (prior month)	10 (5–15)	9 (4–24)
Charge for anal sex with a condom, (median, IQR)	50,000 (50,000 – 100,000)	100,000 (40,000 – 150,000)
Charge for anal sex without a condom, (median, IQR)	87,500 (50,000 – 150,000)	100,000 (50,000 – 250,000)
Currently using PrEP		
Yes	5 (12)	7 (17)
No	36 (88)	34 (83)



# High intervention feasibility and acceptability

<b>HIV self-test feasibility and acceptability</b>	<b>M3</b>	<b>M6</b>	<b>M9</b>	<b>M12</b>
Received self-test kit from peer	97%	100%	93%	91%
Used self-test kit	97%	100%	100%	100%
Self-tested at home	94%	94%	93%	91%
<b>STI self-sampling feasibility and acceptability</b>				
Received STI self-sampling kit from peer	83%	100%	93%	89%
Used self-sampling kit	100%	100%	100%	100%
Found self-sampling kit very easy or easy to use	100%	100%	100%	100%
Confident showing someone how to self-collect samples	100%	97%	100%	97%
Would recommend self-sampling to others	100%	91%	100%	90%

Feasibility – proportion of expected HIVST and STISS kits delivered by peers

Acceptability – measured using 5-point Likert scales

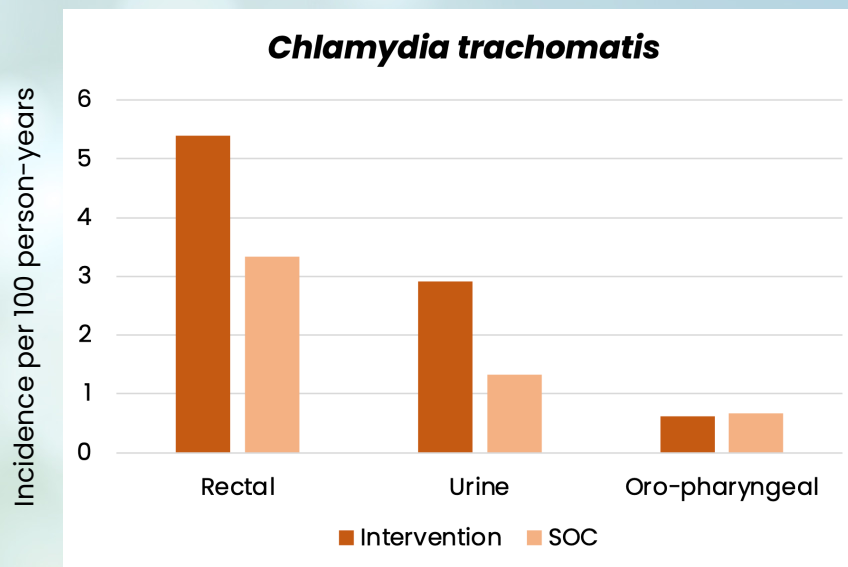
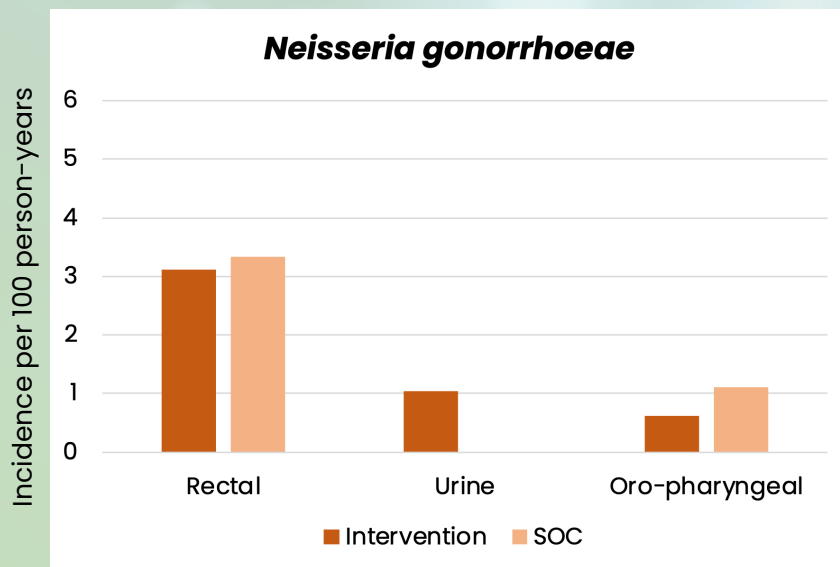


# Primary Results

Intervention Effect on PrEP Adherence	Incidence Rate Ratio (95% CI)	P
Tenofovir $\geq 700$ fmol/punch in DBS SOC Intervention	Ref 0.84 (0.42–1.68)	0.61
Tenofovir $>1,500$ ng/ml in urine SOC Intervention	Ref 0.97 (0.86–1.09)	0.63
Intervention Effect on Sexual Behavior		
Condomless sex SOC Intervention	Ref 0.97 (0.91–1.04)	0.39



# STI incidence



- No HIV seroconversions were observed during the study
- Four TGW acquired HIV after study exit following incarceration



# Discussion

- Randomized trial of peer delivered HIVST and STISS found no effect on oral PrEP adherence or sexual behaviors among TGW in Uganda
  - Oral PrEP taken at levels insufficient to achieve HIV protection
  - Long-acting PrEP formulations could motivate sustained PrEP use for TGW
- High acceptability of HIVST and STI self-sampling
  - Nearly all used HIVST and self-collection kits
- Peer delivered combination HIV prevention feasible in this setting
- Choice-based PrEP delivery (i.e., newer PrEP formulations/delivery models/trans-friendly care) could support PrEP use by TGW



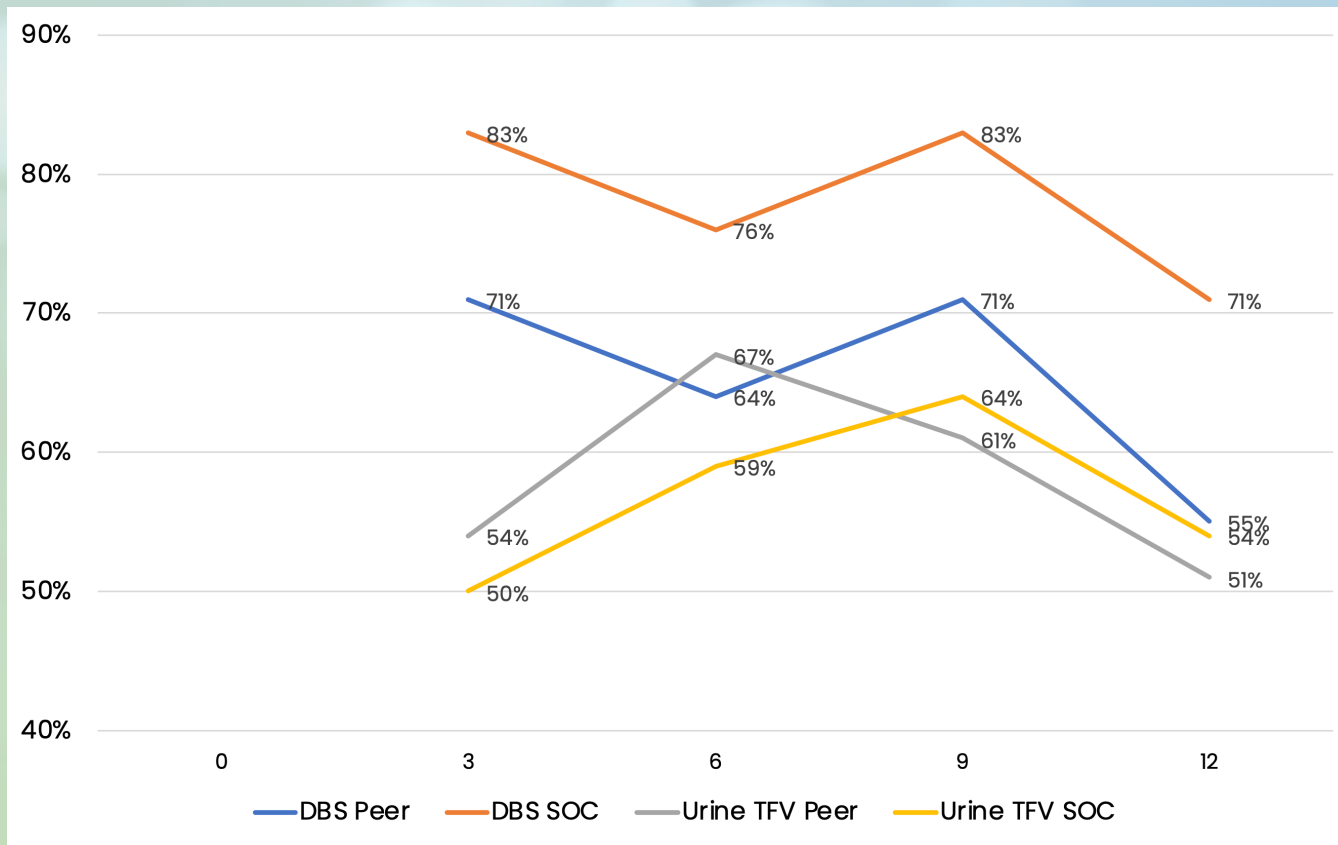
# Acknowledgements

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# PrEP adherence by TFV in DBS and urine #ADHERENCE2023



TFV (tenofovir); DBS (any TFV detection in dried blood spots); Peer (Peer-delivery arm); SOC (standard of care arm)