



# PrEP uptake and adherence among transgender women: findings from an RCT of a multicomponent intervention (HPTN 091)

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# SUMMARY SLIDE

## Main question

Does co-location of PrEP with gender affirming hormone therapy (GAHT) and strengths-based peer health navigation (PHN) improve PrEP uptake and adherence among transgender women?

## Findings

PrEP engagement was high among *all* participants. Co-location and structured PHN sessions were not associated with PrEP uptake or adherence.

## Importance

In the context of supportive, affirming clinical environments, PrEP providers have flexibility to co-locate services or link to external GAHT.

## PLOS ONE


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**98 published studies**  
48,604 TW from 34 countries

- Prevalence **19.9%**
- Odds Ratio **66.0**

### RESEARCH ARTICLE

The worldwide burden of HIV in transgender individuals: An updated systematic review and meta-analysis

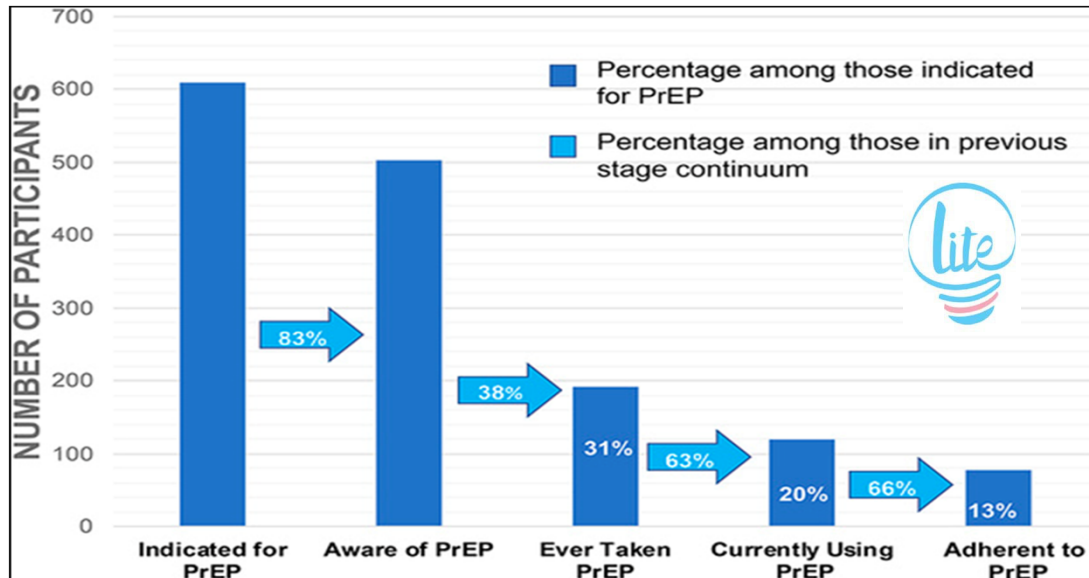
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# PrEP Continuum in Transgender Women

Globally, PrEP willingness is high (~80%), but uptake and adherence are low (~35%)



Baseline data from U.S. LITE cohort of trans women without HIV

Barriers include:

- Hardship, stigma, distrust

Facilitators include:

- Social cohesion, hormone therapy

# Gender Affirmation Framework



Sevelius JM et al. *Journal of the International AIDS Society* 2016, **19**(Suppl 6):21105  
<http://www.jiasociety.org/index.php/jias/article/view/21105> | <http://dx.doi.org/10.7448/IAS.19.7.21105>



## Review article

# The future of PrEP among transgender women: the critical role of gender affirmation in research and clinical practices

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# HPTN 091: Interventions

## PrEP & STI Screening



## Gender Affirming Hormones & Peer Health Navigation (6 sessions)



Session Four: Keeping it Together ....

Session Five: Work It! .....

Session Six: Healthy Dival! .....

Session One: Let's Be Real .....

Session Two: Be Fierce .....


Session Three: Get It? .....

## Co-Location of PrEP and Gender Affirming Care

COMMENT | VOLUME 6, ISSUE 9, E566-E567, SEPTEMBER 2019

## Transgender HIV research: nothing about us without us

[Ayden I Scheim](#)  • [Max Nicolai Appenroth](#) • [S Wilson Beckham](#) • [Zil Goldstein](#) • [Mauro Cabral Grinspan](#) • [JoAnne G Keatley](#) • et al. [Show all authors](#)

Published: August 19, 2019 • DOI: [https://doi.org/10.1016/S2352-3018\(19\)30269-3](https://doi.org/10.1016/S2352-3018(19)30269-3) •  Check for updates

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 PlumX Metrics

Peer-led intervention  
Trans-identified protocol co-chair  
Community working group consultations  
Site-based community consultations  
Responsive to community feedback



# Community Consultations & Responsiveness

## Previous design:

- Randomize 1:1 to intervention vs SOC arms for 12 months



## Revised design:

- Randomize 1:1 to *immediate* vs. 6-month *deferred* intervention arms
- Extend study follow-up to 18 months
  - All participants receive PrEP and hormones for 12 additional months

## Additional concerns from community consultations:

- Ability to continue with current medical provider
- Linkages to services for participants in deferred arm
- Access to PrEP and hormones when the study is over



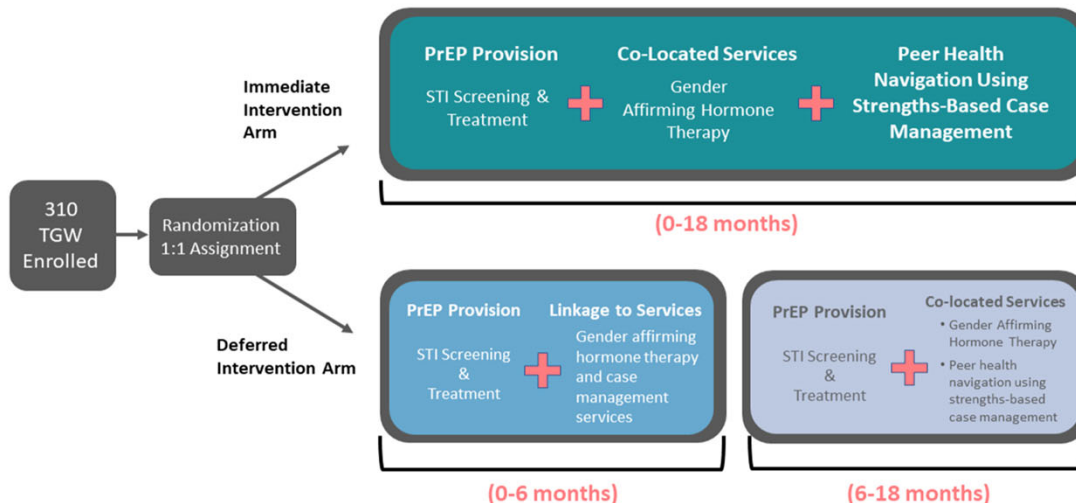
- Participants could **continue with current medical providers** and participate
- Comprehensive **linkage and referral** plans for each site to gender-affirming hormone therapy and other services
  - Deferred arm during the study
  - All participants after the study



# HPTN 091: Aims & Design

## Primary Aims:

- To assess acceptability and feasibility of delivering integrated gender affirming care and HIV prevention services
- To assess PrEP uptake and adherence by study arm



- **Study visits (every 3 months)**
  - Medication refills: PrEP +/- GAHT
  - Laboratory tests: HIV, STI, safety labs
  - CRFs and ACASI: self-report
- **Primary Outcome Data**
  - TFV levels (measure of adherence)
  - Survey responses (sexual behaviors)
  - **2 FGDs with 8 peer navigators**

- Bridge HIV, San Francisco, CA
- Harlem Prevention Center, New York, NY
- Penn Prevention, Philadelphia, PA
- Houston AIDS Research Team, Houston, TX
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC), Rio de Janeiro, Brazil

# Baseline Participant Characteristics

Characteristic	Overall (N=304)	Immediate Arm (n=149)	Deferred Arm (n=155)
Age in years (median, IQR, range)	28 (25, 35)	27 (25, 35)	29 (24, 36)
Race & ethnicity (n, %)			
Hispanic/Latina	163 (54%)	82 (55%)	81 (52%)
Black	96 (32%)	46 (31%)	50 (32%)
White	107 (35%)	53 (36%)	54 (35%)
Education			
High school graduate or higher	238 (79%)	116 (78%)	122 (79%)
Enough money for housing, food, and utilities	165 (54%)	84 (56%)	81 (52%)
Ever homeless, n (%)	152 (50%)	77(52%)	75 (48%)
Went to sleep hungry in last 30 days, n (%)	87 (29%)	44 (30%)	43 (28%)

# Baseline Participant Characteristics



Characteristic	Overall (N=304)	Immediate Arm (n=149)	Deferred Arm (n=155)
<b>Gender Affirmation</b>			
Ever on GAHT, n (%)	250 (82%)	123 (83%)	127 (82%)
Baseline GAHT use, n (%)*	124 (41%)	59 (40%)	65 (42%)
<b>Sexual Behavior</b>			
Condomless sex past 3 mo, n (%)	151 (50%)	74 (50%)	77 (50%)
Substance use during sex past 3 mo, n (%)	137 (45%)	59 (40%)	78 (50%)
Ever sex work, n (%)	150 (49%)	77 (52%)	73 (47%)
<b>PrEP Use</b>			
Baseline PrEP use, n (%)	34 (11%)	18 (12%)	16 (10%)
PrEP acceptance at enrollment, n (%)	222 (73%)	105 (71%)	117 (76%)

\*Baseline GAHT for Deferred arm calculated at week 26 when they become eligible for co-located services and PHN

# Results: Uptake and Adherence

Week 26 Results, n (%)	Overall (N=304)	Immediate Arm (n=149)	Deferred Arm (n=155)	P-values
Study Retention	260 (86%)	125 (84%)	135 (87%)	0.43
Completed ≥ 1 Peer Health Navigation session		147(99%)	<b>1 (1%)<sup>a</sup></b>	<0.0001
PrEP Uptake	262 (86%)	127 (85%)	135 (87%)	0.64
Self-reported PrEP adherence last 3 months	186/260 <sup>b</sup> (72%)	86/125 (73%)	100/135 (74%)	0.35
TFV-DP above lower limits of detection	199/260 <sup>b</sup> (77%)	93/124 (73%)	104/135 (77%)	0.43
TFV-DP > 4 pills per week	132/260 <sup>b</sup> (51%)	63/125 (50%)	69/135 (51%)	0.91

<sup>a</sup> One participant had first PHN session prior to start of 26 weeks

<sup>b</sup> Denominator includes only participants who had initiated PrEP *at the clinic* by week 13

# Results: Focus Groups

## Peer Health Navigators (PHNs): Focus Group Results

- In addition to conducting peer navigation sessions by arm, PHNs engaged in recruitment and retention activities with *all participants*, regardless of arm
- PHNs “improvised” the peer navigation curriculum to *meet the participants’ needs*: “Guidelines for PHN went out the window”
- PHNs often provided support well beyond structured sessions to any participant in need (e.g., name change, food stamps, mental health): “I would go further than information being shared. *Resources were being shared.*”
- Participants shared information and resources across study arms; including hormones. Desire to “build a trans family” – *community-building* encouraged by the peer navigators, “together we are stronger than we imagine”

# Conclusion

- PrEP engagement was high among all participants
  - Peer support available to ALL participants, regardless of arm or PHN
  - Referrals available to ALL participants, regardless of arm or PHN
- Co-location and structured PHN sessions were not associated with PrEP uptake or adherence
- Findings highlight flexibility available to PrEP programs
  - Co-locate or facilitate access to external GAHT
  - Context of peer support and gender-affirming environment

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