Engaging community stakeholders in preparation for HPTN 091, a study integrating HIV prevention, gender-affirming medical care, and peer health navigation to prevent HIV among transgender women in the Americas

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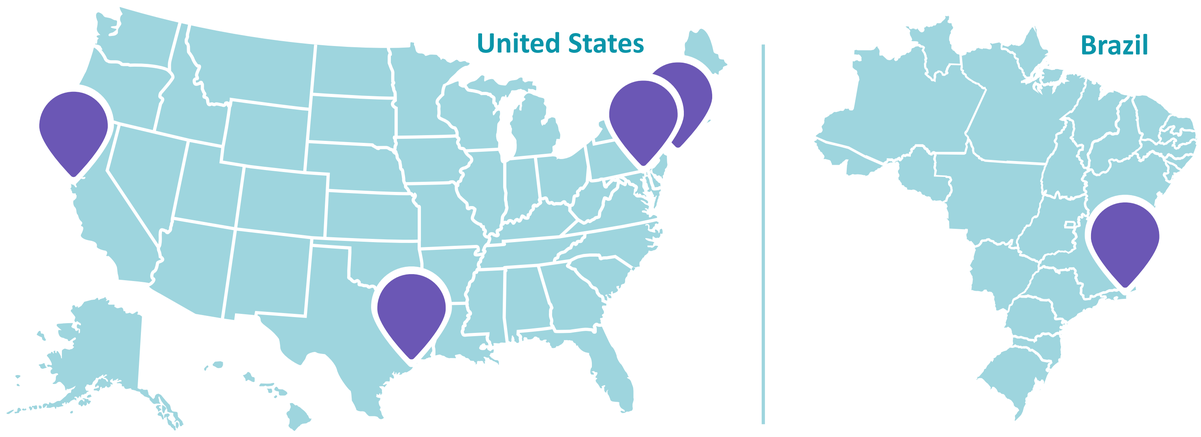
BACKGROUND

- Transgender women (TGW) worldwide are disproportionately affected by HIV, with an estimated prevalence of 19.9%.
- TGW suffer high rates of trauma and violence, as well as stigma and discrimination, resulting from transphobia.
- These experiences are exacerbated by intersecting stigmatized attributes such as race and ethnicity.
- Multiple sociocultural and structural barriers contribute to adverse HIV prevention outcomes.
- While research indicates that TGW have positive attitudes toward pre-exposure prophylaxis (PrEP), a biomedical HIV prevention strategy, awareness and uptake are low.
- Uptake barriers include HIV-related stigma, sexual behavior stigma, and drug-hormone interaction concerns.
- Given TGW's unique/individualized HIV prevention needs, it is critical that TGW be consulted and have direct input throughout the research process for HIV prevention interventions.



Interactive, participatory processes enabled stakeholders to provide guidance to researchers to redesign the protocol to include access to gender-affirming hormone therapy for all participants and strengthen strategies related to PrEP provision and strengths-based peer health navigation.

METHODS

HPTN 091, the I Am study, was a multi-site, open-label trial that assessed the feasibility, acceptability, and preliminary impact of a multi-component strategy that provided HIV prevention services, gender-affirming hormone therapy, and peer health navigation (PHN) to increase uptake and adherence to PrEP. The study enrolled approximately 310 TGW, 18 years of age or older, who were not living with HIV.

In preparation for study implementation, HPTN 091 conducted 5 community consultations in New York, Houston, San Francisco, Philadelphia, and Rio de Janerio, engaging a total of 138 transgender attendees. Consultations facilitated diverse audience dialogue, detailed explanations of TGW's HIV prevention needs, and elicited stakeholder questions/recommendations regarding study design and implementation of HPTN 091 prior to protocol finalization.

The original study design:

- TW not living with HIV (~estimated 384) will be randomized 2:1 to the intervention arm or the SOC arm. HIV prevention services will be provided including risk-reduction counseling and PrEP.
- TW living with HIV (~estimated 96) will be randomized 2:1 to the intervention arm or the SOC arm. They will be referred for linkage to care and treatment, if not currently engaged in care.
- Peer Health Navigation and hormone administration will be provided in each of the intervention arms.

Figure 1. HPTN 091 Original Study Design

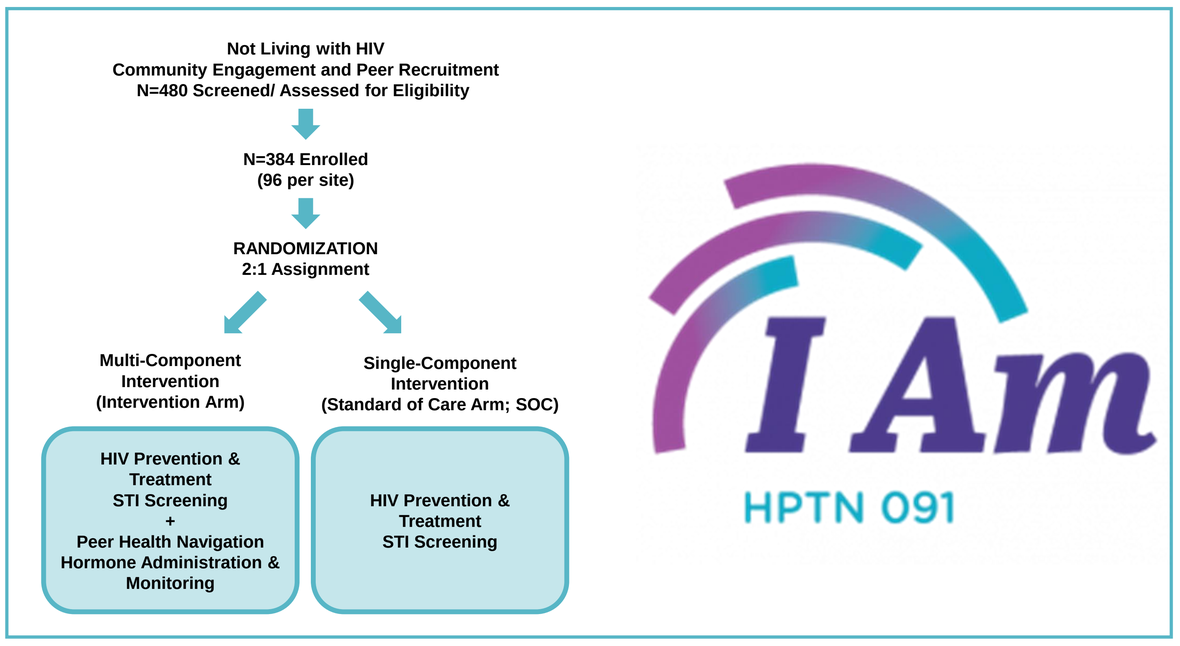
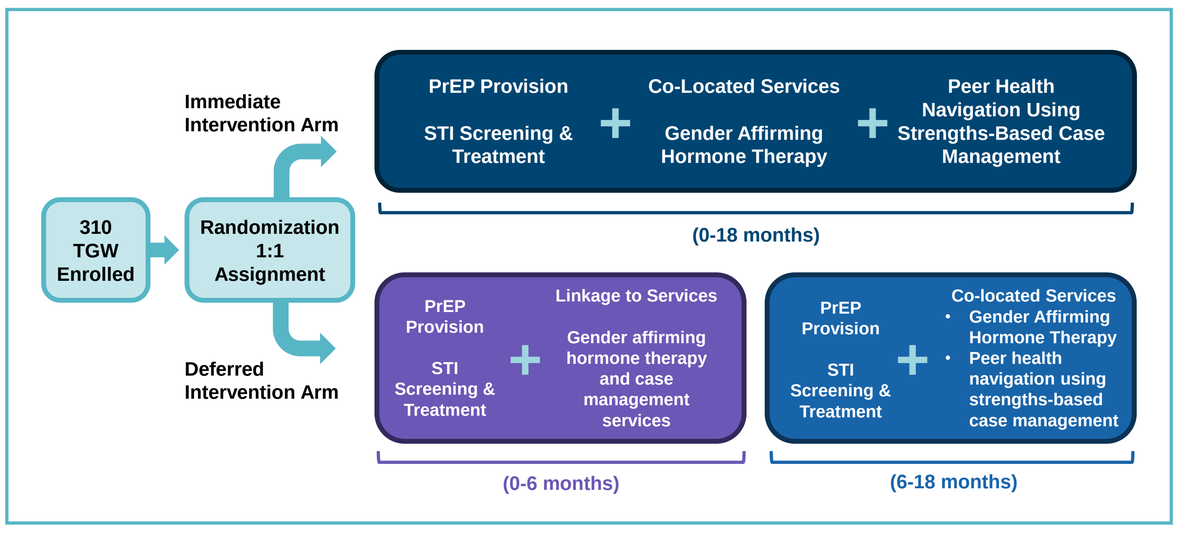


Figure 2. HPTN 091 Revised Study Design



RESULTS

- Participants discussed facilitators and barriers to study participation based on their lived experiences and local knowledge of community norms, including the need for non-stigmatizing gender-affirming healthcare and trauma-informed strategies to optimize HPTN 091 participation for TGW.
- The interactive, participatory processes enabled stakeholders to express strong concerns related to the study design (refer to figure 1) and work with researchers to redesign the protocol to include access to gender-affirming hormone therapy for all participants and strengthen strategies related to PrEP provision and strengths-based PHN (refer to figure 2). The revised study design:
  - Study participants were randomized 1:1 to the Immediate Intervention arm or the 6-month Deferred Intervention arm.
  - Both arms received PrEP as well as screening and treatment for sexually transmitted infections (STIs).
  - Participants in the Immediate Intervention Arm received gender-affirming medical care and PHN using strengths-based case management (SBCM) beginning at the time of enrollment.
  - As part of the Deferred Intervention Arm, participants were provided linkages to external gender-affirming medical care and case management services during the deferral period and were able to transition to the study intervention six months after the enrollment visit (refer to figure 2).
- Better than expected screening to enrollment ratios and retention rates were attributable in part to proactive interactions with community representatives and feedback received.

CONCLUSIONS

- HPTN recognizes that research success requires partnerships with local implementers, potential participants, and community advocates.
- Community partnerships facilitate early ownership of research by key stakeholders.
- Inclusion of local perspectives of TGW provided the research team generous insights into the development and implementation of a culturally appropriate HIV prevention integrated strategy and added value to a wide range of trial considerations through transparent, authentic dialogue.
- Community engagement was key to achieving enrollment goals and high retention rates for the study.

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