Potential Impacts of Participating in an HIV Cure–Related Trial With an Analytical Treatment Interruption on Partners: Qualitative Research Findings

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Conclusions

- About one-half of the people with HIV who were interviewed in this study did not anticipate major impacts on their current or future partners if they chose to participate in the hypothetical HIV cure–related trial
- Nevertheless, approximately one-third of people with HIV mentioned potential negative impacts on current or future partners, including emotional stress due to possible loss of viral suppression and having to make shared decisions about safety, trust, and sexual practices
- Provision of a warm referral for preexposure prophylaxis (PrEP) to intimate partners may affect the decision of some people with HIV to participate in the hypothetical trial

Plain Language Summary

- This study looked at the ways people with HIV viewed how joining a hypothetical clinical trial aimed at finding a cure for HIV might affect their partners
- The hypothetical trial would involve stopping all HIV medication for a period of time, which is known as an "analytical treatment interruption"
  - During this interruption, HIV levels in the body could go up, which increases the risk of passing HIV to a partner
- About half of the people with HIV believed that their partners would not be affected if they participated in a hypothetical trial with an analytical treatment interruption
- Some people with HIV said it would be important to talk to their partners about the risks before joining
- People with HIV had mixed views on whether offering their intimate partners access to medicine that prevents HIV infection would affect their own decision to take part in the hypothetical trial
- Overall, the study shows that careful planning and ongoing support are essential for running a clinical trial for an HIV cure that balances the benefits and risks for those who volunteer to participate

Introduction

- Adherence to antiretroviral therapy (ART) is necessary for people with HIV (PWH) to maintain viral suppression and thus prevent disease progression and reduce the risk of HIV transmission[1]
- ART adherence may be challenging for various reasons, including stigma, mental health conditions, and factors associated with oral daily dosing (eg, pill fatigue, logistical challenges),[1,2] highlighting the need for approaches that offer medication-free intervals
- HIV cure research may involve a clinical trial encompassing an experimental intervention followed by an analytical treatment interruption (ATI) to assess the efficacy of the intervention[3]
  - However, recruitment for such trials can pose a challenge due to various concerns, including those related to viral rebound and the subsequent risk of HIV transmission to sexual partners[4]
- Preexposure prophylaxis (PrEP) for sexual partners of PWH who are undergoing an ATI may reduce the risk of HIV transmission in the event of viral rebound[5]
- Perspectives of PWH are needed to inform clinical trial design to optimise PWH participation and contribute to the global effort to end the HIV epidemic

Objective

- To understand the perspectives of PWH on how their participation in a hypothetical HIV cure–related trial that includes an ATI may theoretically affect their partners

Methods

- We conducted in-depth virtual interviews with 72 PWH between June 2024 and February 2025
  - Six PWH per country were interviewed from Argentina, Australia, Canada, the Dominican Republic, France, Germany, Italy, South Africa, Spain, and the United Kingdom, and 12 PWH were interviewed from the United States (in English or Spanish)
  - A subset of PWH from the United States (n = 8) participated in focus groups
- Moderators described to PWH a hypothetical HIV cure–related trial design that included 2 phases: (1) a period during which participants would take their current ART as well as an experimental intervention, followed by (2) an ATI during which all of the medications, including ART, would be stopped
- We asked open-ended questions regarding how PWH perceived their participation in a hypothetical trial involving an ATI might affect any current or future partners or their relationship with any current or future intimate partners (**Figure 1A**)
- For participants from outside the United States and all focus group participants (n = 68), we asked open-ended questions about the potential provision of PrEP or reliable PrEP referral support to their intimate partners as part of participation in the hypothetical trial (**Figure 1B**)
- We used MAXQDA, a qualitative data analysis software program, for thematic analysis of interview transcripts
  - We used an inductive approach to analysing the interviews in order to allow for patterns and themes to emerge directly from participants' interviews

Figure 1. Partner-Related Questions in the Interview and Focus Group Discussion Guides[a]

A.

Impact of clinical trial participation on sexual, intimate, or romantic partner(s)

- We want to better understand how **participation in a clinical trial** like this one **may impact any sexual partner(s)** you may have now or potentially in the future. How might the **requirements of this study impact your partner(s)**?
- How would this trial impact your **sex life or relationships with your intimate partner or partners**?
- If applicable, how might **participation in a clinical trial** like this one impact you around **pursuing and engaging with a romantic partner**?

B.

Provision of PrEP or reliable PrEP referral support for intimate partner(s)[b]

- PrEP (preexposure prophylaxis) is a medication for people who do not have HIV that prevents HIV infection. It requires taking a pill every day, or an injection every month or two, depending on the medication.
- If it were possible for the partner(s) you are intimate with to **get PrEP directly**, or **easily get a referral for PrEP**, as part of your participation in this trial, would this **influence your decision**?
- How might this support **impact your partner(s) emotionally**? What about **physically**?
- How might this support affect your **intimate life with your partner**?

[a]Only select questions are included. There was some variability in the questions across the 3 discussion guides (US interviews, US focus groups, non-US interviews); a composite version is shown in the figure. [b]This section of questions was only included in discussion guides for the US focus groups and non-US interviews.
PrEP, preexposure prophylaxis.

Results

Study Participants

- Characteristics of PWH participants are summarised in **Table 1**

Table 1. Participant Characteristics (N = 72)

Age, y	
Median (Q1, Q3)	48.5 (38.0, 58.3)
≥55, n (%)	27 (38)

Sex and gender	n (%)
Sex at birth	
Male	53 (74)
Female	19 (26)
Gender	
Man	53 (74)
Woman	19 (26)

Sexual orientation[a]	n (%)
Lesbian or gay (homosexual)	27 (38)
Straight (heterosexual)	36 (50)
Bisexual	3 (4)
Queer	2 (3)
Other	1 (1)

HIV history	n (%)
Year of HIV diagnosis, 2016-2025	20 (28)
Time on HIV medication, y	
1-2	2 (3)
3-5	11 (15)
6-9	12 (17)
≥10	47 (65)
Last CD4 test was <6 mo ago[b]	49 (82)
Last HIV-1 viral load test was <6 mo ago[b]	50 (83)

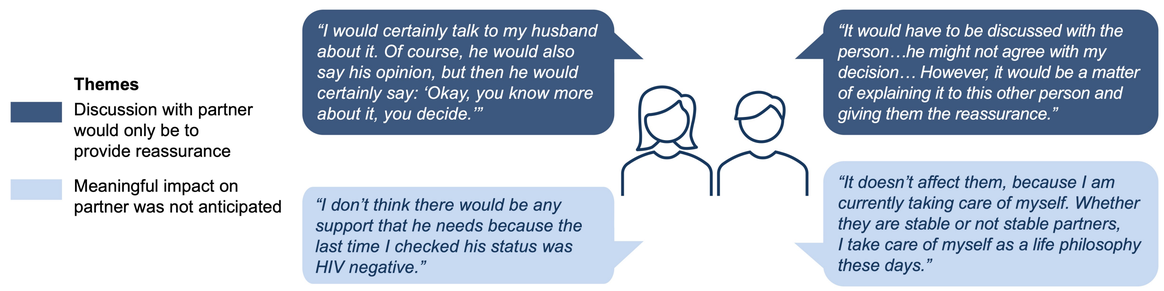
Relationships	n (%)
Marital status[c]	
Divorced, separated, or widowed	7 (10)
Living with partner or married	22 (31)
Single, never married	41 (57)
Has primary/regular partner[d]	33 (46)
Know partner's HIV status[e]	33 (100)
Has any partners with whom the individual has been intimate for ≤6 mo[b,f]	13 (18)

[a]Three PWH preferred not to answer. [b]This question was only asked of PWH outside the United States; thus, the percentage was based on a denominator of 60 PWH. [c]Two PWH preferred not to answer. [d]Four PWH preferred not to answer. [e]Percentage was based on PWH who had a primary/regular partner. [f]Seven PWH preferred not to answer.
PWH, people with HIV; Q1, first quartile; Q3, third quartile.

Impact of Participation in the Hypothetical Clinical Trial on Partners

- **Figure 2** shows selected responses of PWH to discussion questions related to how they perceived their participation in a hypothetical trial that includes an ATI would impact their current or future partners

Figure 2. Perspectives of PWH on the Impact of Participating in the Hypothetical Trial With an ATI on Their Partners



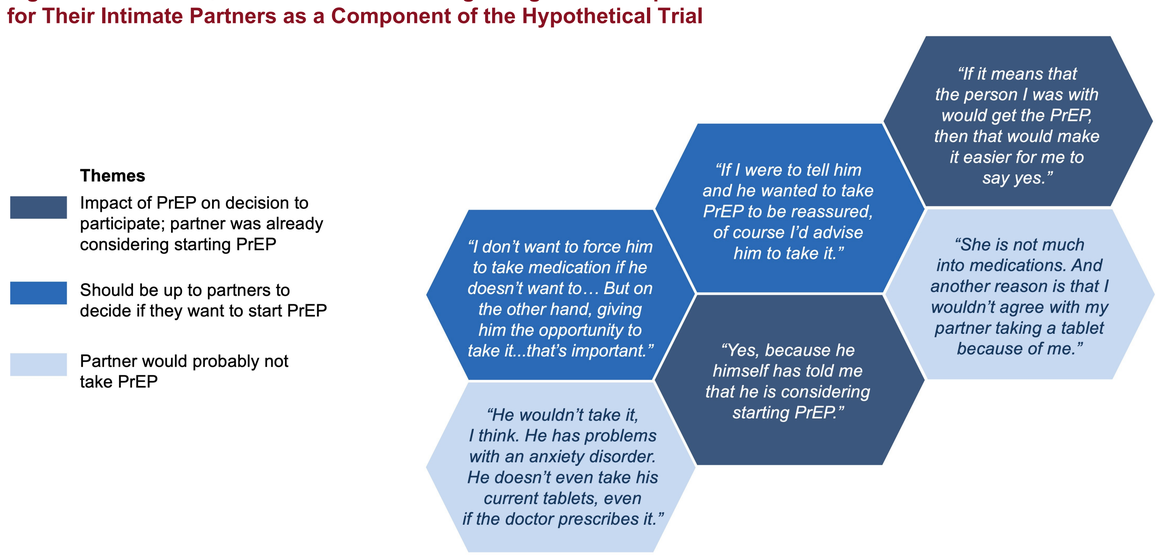
ATI, analytical treatment interruption; PWH, people with HIV.

- Approximately half of PWH (40/72; 56%) did not anticipate that their own trial participation would meaningfully affect their partners
- PWH believed their partners would be supportive, indicated enrolling would be their own decision, and did not expect their partners to be emotionally or practically affected (eg, by needing to adjust routines or take on additional responsibilities)
- Overall, 24 of 72 PWH (33%) mentioned potential negative impacts on partners
  - Specifically, PWH raised concerns about the need for open communication about risks, potential emotional stress due to possible loss of viral suppression, and shared decision-making around safety, trust, and sexual practices
- Some participants emphasised that if they were to talk with their partners, it would be to provide reassurance and not because they expected the intimate partners to be affected by the trial

PrEP Provision or Referral for Partners

- **Figure 3** shows selected responses of PWH to discussion questions related to provision of or referral for PrEP for their intimate partners as part of the hypothetical clinical trial

Figure 3. Selected Quotations From PWH Regarding Their Perspectives on Provision of or Referral for PrEP for Their Intimate Partners as a Component of the Hypothetical Trial



PrEP, preexposure prophylaxis; PWH, people with HIV.

- Where the potential for PrEP provision or referral was mentioned, a subset of participants (15/68; 22%) indicated that this would be up to their intimate partners to decide
- While some PWH (13/68; 19%) indicated that provision of PrEP to their intimate partners would influence their own decision to participate in the trial, more (27/68; 40%) said that it would not
- Some PWH (10/68; 15%) appreciated the added layer of security but still stressed that it had to be their intimate partners' choice
- Others pointed out that their intimate partners would likely not want PrEP, citing aversion to taking medication or the inconvenience of a new routine
  - Their intimate partners' own attitude toward medicine also made it an unlikely option

Limitations

- The study only queried participants regarding PrEP initiation
  - Topics related to PrEP maintenance are also important, as behaviours can be dynamic
  - Future research should assess preferences and uptake for different PrEP modalities, including oral daily, long-acting injectable, on demand, and other forms
  - Greater attention should also be given to gender dynamics
- The study did not capture the HIV status of participants' sexual partners
  - In addition to sexual partners without HIV, those with HIV can be affected by ATIs, such as by experiencing concerns about maintaining viral suppression and by not wanting to interfere with trial outcomes (including potential viraemia)

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