Balancing Vulnerability and Freedom: Perspectives on HIV Cure-Related Trials With Analytical Treatment Interruption Among People With HIV and Healthcare Providers in the United States

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Conclusions

- These data demonstrate that perspectives of people with HIV (PWH) are mixed regarding participation in a trial with an analytical treatment interruption (ATI)
- Perceived benefits included freedom from side effects, anxieties, or stigma associated with daily treatments for HIV
- PWH and healthcare providers (HCPs) both expressed concerns about the risk of detectable viral loads, the possibility of HIV transmission, and the possibility of antiretroviral therapy (ART) resistance during an ATI
- These findings highlight the delicate balance between the increased freedom and heightened vulnerability that might be experienced during an ATI, underscoring the need for careful study design, and education and support of participants during an HIV trial with an ATI

Plain Language Summary

- This study explored how people with HIV (PWH) and healthcare providers (HCPs) view temporary stops in HIV treatment during research toward an HIV cure, referred to as analytical treatment interruptions (ATIs)
- Researchers interviewed 12 PWH and 5 HCPs and held 2 focus groups with PWH in 2024
- PWH expressed varied opinions. While HIV cure-related trials with ATIs offered more freedom from daily medication and its impacts, participants also were concerned with possible negative consequences
- Both PWH and HCPs were concerned about HIV becoming detectable again, the risk of HIV transmission, and long-term health effects
- This study shows that participation in an HIV cure-related trial with an ATI requires careful planning, clear communication, and ongoing support. The goal is to balance benefits and risks, ensuring the safety and well-being of the participants

References: **1**. Bouabida K, et al. *Front Reprod Health.* 2023;5:1201087. **2**. de Los Rios P, et al. *AIDS Behav.* 2021;25:961-72. **3**. Julg B, et al. *Lancet HIV.* 2019;6:e259-68.

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Introduction

- The global fight against HIV continues with a search for a cure
- For PWH, adherence to ART remains crucial for treatment efficacy, but many individuals struggle with adherence due to stigma and mental health challenges[1]
- While ART has dramatically improved outcomes for PWH, daily dosing schedules present ongoing challenges including pill fatigue, constant reminders of HIV status, logistical complications in daily life, and a significant long-term healthcare burden, which all highlight the need for treatment strategies offering medication-free intervals[2]
- As HIV cure research advances, clinical trials with an ATI become increasingly important. However, recruitment remains challenging due to specific eligibility criteria and potential risks, including the possibility of CD4 cell count decrease, adverse health effects from treatment cessation, and concerns about viral rebound[3]
- This study explored perspectives of PWH and HCPs regarding their hypothetical participation in a potential HIV cure-related trial with an ATI
- These perspectives can inform future strategies for designing clinical trials that will optimize PWH and HCP participation and contribute to the global effort to end the HIV epidemic

Methods

- Qualitative 60-minute semi-structured virtual interviews with 12 PWH and 5 HCPs (**Table 1**) were conducted in the USA from June to July 2024
- Two 2-hour semi-structured virtual focus groups with PWH (n = 3 and n = 5) were held in August 2024 to further explore participation in a hypothetical HIV cure trial with an ATI
- Thematic analysis of transcripts was done using qualitative data analysis software

Table 1. Characteristics of Interview and Focus Group Participants

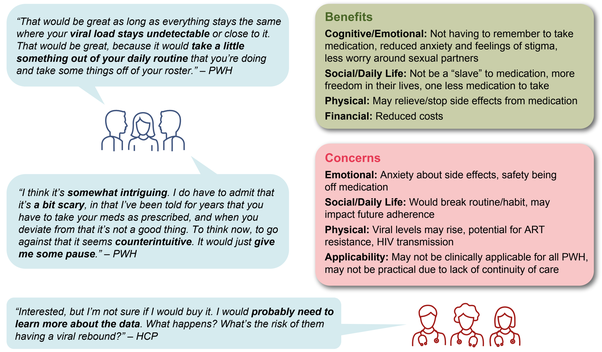
PWH (n = 12)		n
Age, years	18-24	1
	25-34	4
	35-44	3
	45-54	2
	> 55	2
Race	Black or African American	6
	White	5
	Other	1
	Hispanic (yes)	4
	Hispanic (no)	8
Sex at birth	Male	9
	Female	3
Years on HIV medication	3-5	4
	6-9	2
	> 10	6

HCPs (n = 5)		n
Specialty	Family/general medicine	3
	Infectious disease	2
Years treating HIV	6-10	1
	> 10	4

Results

- Both PWH and HCPs expressed mixed perspectives about ATI, with potential benefits including reduced medication burden, anxiety, and costs, and potential concerns about viral rebound, resistance, and transmission risks (**Figure 1**)

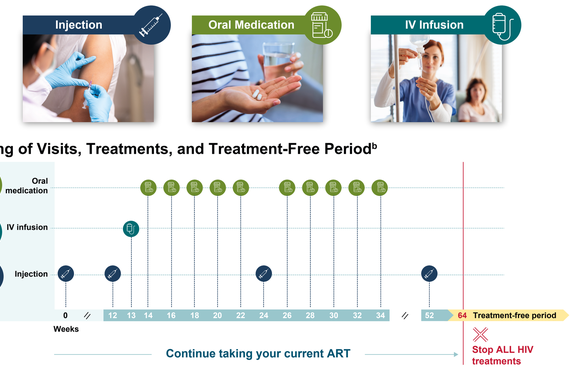
Figure 1. PWH and HCP Initial Perspectives on ATI



- Overall, PWH expressed willingness to consider a novel treatment regimen with an ATI; influential key factors included continued monitoring, physician recommendations, and maintained viral suppression
- PWH preferred a minimum ATI duration of 6 months. Some said 18-24 months would be "great" and "exciting," and some said the "longer the better"
- PWH emphasized that an undetectable viral load and ongoing medical monitoring were more important than the length of time off treatment. Some expressed concerns about safety and potential resistance to ART
- HCPs identified potential barriers to recommending ATI, emphasizing its potential suitability for specific patient types (eg, frequent travelers, those with busy schedules) and highlighting influential factors such as trust in the PWH, continuity of care, and need for more supporting data
- While minimum acceptable ATI durations ranged from 1-6 months, HCPs had concerns about viral suppression, side effects, efficacy, and transmission risk, underscoring the need for comprehensive patient assessment and robust clinical evidence
- PWH and HCPs were presented with a hypothetical HIV cure trial (**Figure 2**)

Figure 2. Hypothetical HIV Cure-Related Trial Overview[a]

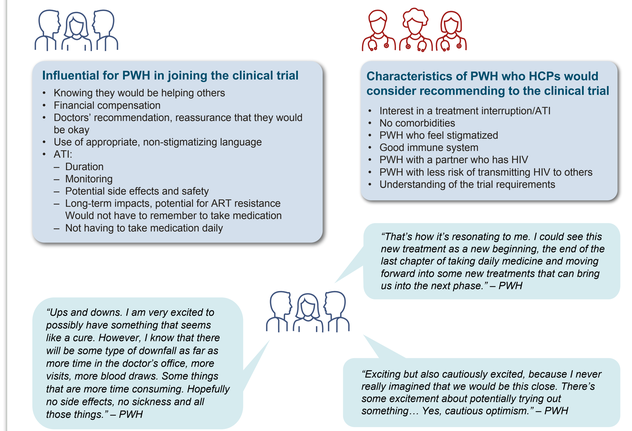
This study is testing whether new medications will allow the body to control HIV without HIV medications for weeks to months. Participants would continue to take their current HIV medications, and also receive new medications, which may include:



[a]Shown to participants during interviews and focus groups. [b]"Treatment-free period" was used instead of "ATI" during interviews and focus groups.

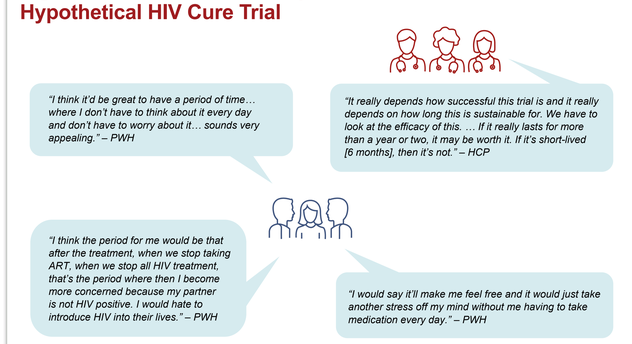
- PWH felt "hopeful" and "excited" at the possibility of an HIV cure clinical trial; influential factors included knowing they would be helping others and receiving financial compensation (**Figure 3**)
- Overall, HCPs would recommend the trial to PWH interested in a "treatment holiday" and to those at less risk of transmission (**Figure 3**)

Figure 3. PWH and HCP Initial Perspectives on Hypothetical HIV Cure Trial: Reasons to Participate and Ideal Participants



- Several PWH said an ATI would make them more willing to participate in the proposed clinical trial, highlighting that being off medication would allow them more freedom and convenience (**Figure 4**)
- PWH expressed preferences for convenient monitoring locations such as local pharmacies or laboratory facilities; monthly monitoring during the treatment-free period was considered ideal
- However, some PWH showed reluctance toward at-home monitoring by HCPs and emphasized that overly frequent monitoring (weekly or bi-weekly) could be invasive and potentially deter trial participation

Figure 4. PWH and HCP Perspectives on ATI as Part of a Hypothetical HIV Cure Trial



- PWH expressed concerns about safety in the hypothetical situation where their viral loads did not remain undetectable, although we did not interview intimate partners in this study
- Access to emotional support would be influential in PWH willingness to join the proposed clinical trial, and open lines of communication between participants and study staff would be beneficial
- PWH want flexibility in completing surveys as part of a clinical trial. Survey length may influence preferences around format and frequency

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