Perceptions of Analytical Treatment Interruption Among People With HIV Using Antiretroviral Therapy in the USA

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Conclusions

- **The participants expressed both positive and negative impacts of analytical treatment interruption (ATI)** related to the interruption of standard-of-care HIV-related treatment
- Concerns related to ATI can be used to facilitate discussions between people with HIV (PWH) and their health care practitioners, social workers, and therapists regarding participation in clinical research
- **These results may also inform future trial design, including recruitment and retention strategies**
- Integrating socio-behavioral research, techniques, and tools into ATI protocols can help address participant concerns related to ATIs and potentially improve study outcomes and participant experiences
  - Socio-behavioral research is the scientific study of human behavior, social interactions, and societal factors that influence health outcomes and decision making. This interdisciplinary field combines elements of psychology, sociology, anthropology, and public health to understand and address complex health-related issues
- These data support the **importance of understanding the potential experiences of PWH during a trial**, especially as it relates to the **positive and negative emotional impacts of ATI, and its impact on intimate relationships**

Plain Language Summary

- We interviewed 15 people with HIV (PWH) to understand their **thoughts on stopping HIV treatment temporarily (analytical treatment interruption [ATI]) for HIV cure-related research**
- **Participants reported both positive and negative impacts**, with more positive effects on daily life and work, and more negative effects on emotions and relationships
- Many were worried about the intervention's effectiveness and how it would affect their intimate relationships
- Participants had varied opinions about what a meaningful length of time off treatment would be, with a third saying at least 3 months
- **These findings can help us to understand the potential barriers to or facilitators of participation in clinical trials** faced by PWH and can inform future study designs
- Furthermore, addressing concerns expressed by PWH regarding their potential participation in trials with ATI could help **make ATI trial participation more meaningful and acceptable for PWH**. This approach may ultimately advance scientific progress toward a potential cure for HIV

Background

- In the absence of a validated surrogate marker for HIV cure research, researchers must rely on established disease indicators, primarily plasma HIV RNA levels[1]
- To evaluate the efficacy of potential curative interventions in extending antiretroviral therapy (ART)-free viral suppression, ATI remains the most definitive method for the evaluation of potential regimens for HIV cure in clinical trials[1]
- However, ATIs are not free of risk,[2] and clinical trial participants may experience viral rebound and/or psychosocial consequences of being off treatment. These factors could potentially limit participation in clinical trials

Objective

- Understanding the perceptions of ATI from PWH provides insights that may be incorporated into clinical trial designs and considered in decision making as it relates to participation in cure-related research. Our objective was to explore the perceptions and perspectives of PWH regarding ATI within a clinical trial setting

Materials and Methods

- We recruited all participants through Rare Patient Voice, a health care panel recruitment group that connects patients and family caregivers with researchers
- We conducted qualitative interviews via Health Insurance Portability and Accountability Act (HIPAA)-compliant video conferencing with PWH in the United States currently receiving ART (Figure 1)
- Recruitment aimed to achieve diversity in gender, race, ethnicity, and treatment experience
- Participants were given a hypothetical scenario describing ATI and asked to explain the expected impact of being off standard-of-care HIV treatment
- A timeline was included for when the impact of being off treatment may be meaningful
- We analyzed interview transcripts to identify the most common impacts of ATI and meaningful time related to being off ATI

Results

Participant Characteristics

- We interviewed 15 participants representing various demographic backgrounds (Table 1)
- Most of the participants (80%) were on a single-tablet ART regimen

Participant Feedback (Figure 2)

- Participants reported a total of 30 impacts across 7 domains
- Participants most commonly reported impacts on emotional well-being and relationships with intimate partners (n = 9 of 30, 30% each)
- Among the 30 impacts of ATI reported, 63% (n = 19) were coded as positive and 37% (n = 11) as negative
  - Positive impacts were more often associated with impacts on daily activities, social life, and work/school, whereas negative impacts more often were associated with emotions, specifically concern about efficacy, and partner relationships regarding communication and sexual activity
- The most common reported impacts are presented in Figure 2 with example quotes from participants
- Expected meaningful time off all treatments ranged from 1-2 years, with one-third of participants reporting that they would need to be off treatment for at least 3 months for it to be meaningful

Figure 1. Interview guide content[a]

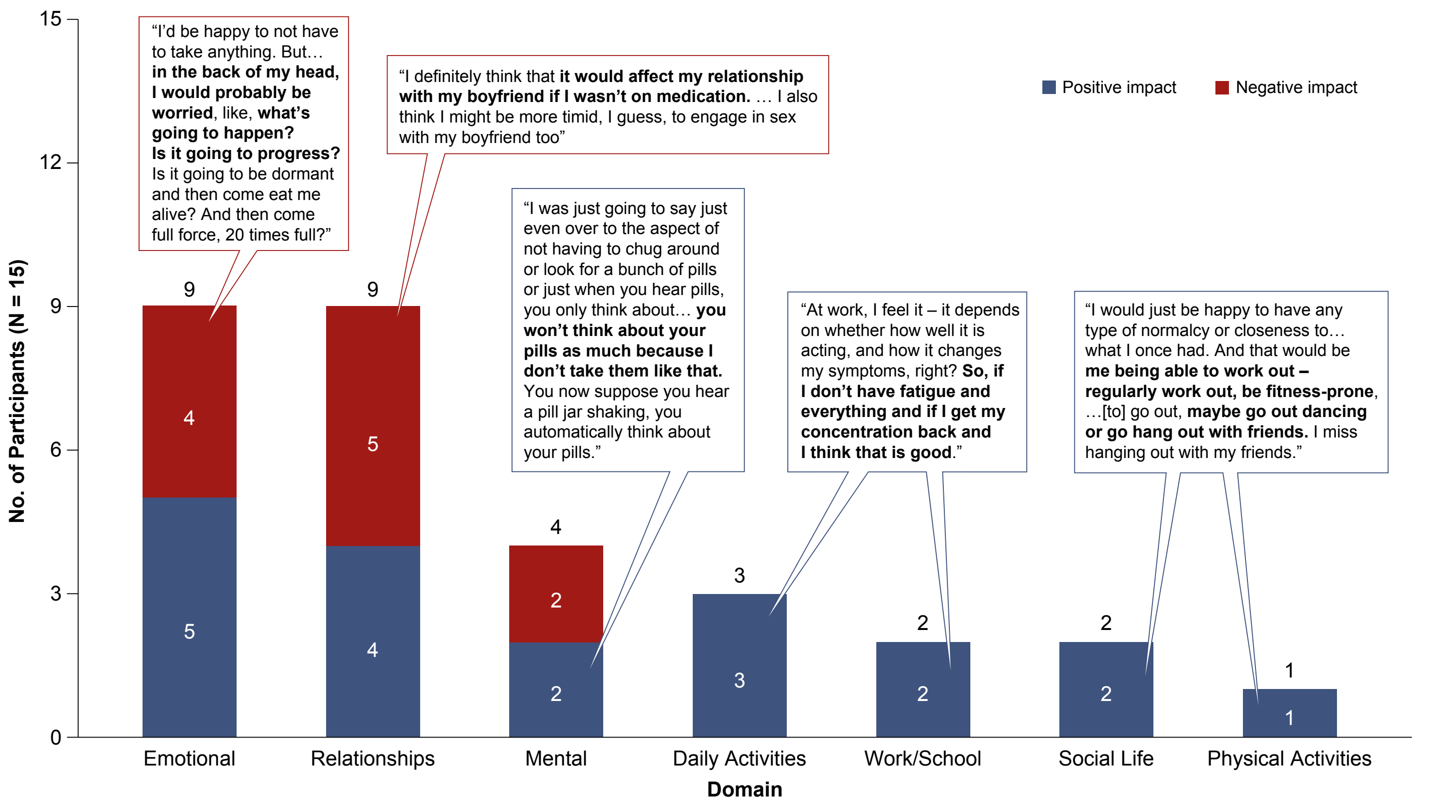
- How do you think you would feel **emotionally** if you stopped taking HIV medicines like I just described? Please explain.
  - Would not being able to take your *[current ART treatment]* during a study like the one I described make you **feel worried or anxious**? If so, why? If not, why not?
- How would being off all HIV-related treatment affect you **mentally**?
- How would being off all HIV-related treatment affect your **daily routine**?
- How would being off all HIV-related treatment affect you **physically**?
- How would being off all HIV-related treatment affect your **social life**?
- How would being off all HIV-related treatment affect your **relationships**?
  - Your **friendships**?
  - Your **intimate partner relationships**?
    - How would you feel about **telling an intimate partner** that you were off all HIV-related treatment if you were part of a study like this?
    - [*If not answered, ask:*] Would being off all HIV-related treatment affect your **sex life**?
- How would being off all HIV-related treatment affect you at **work or school**?
- How else would being off all HIV-related treatment affect you **overall**?

[a]Participants were given time to describe the anticipated impact(s) spontaneously before being questioned by the interviewer.

Table 1. Participant Demographics and Characteristics

	Total Sample (N = 15)
Age, mean (SD), years	43.7 (13.7)
Sex, n (%)	
Male	9 (60.0)
Female	6 (40.0)
Sex assigned at birth, n (%)	
Male	9 (60.0)
Female	6 (40.0)
Gender, n (%)	
Male	8 (53.3)
Female	6 (40.0)
Transgender	1 (6.7)
Race, n (%)	
Black or African American	8 (53.3)
White	7 (46.7)
Asian	1 (6.7)
Education, n (%)	
Some high school (no degree)	1 (6.7)
High school graduate (or equivalent)	2 (13.3)
Some college (no degree)	5 (33.3)
College degree	7 (46.7)
Work status, n (%)	
Part time	6 (40.0)
Full time	5 (33.3)
On disability	4 (26.7)
Homemaker, retired, or unemployed	3 (20.0)

Figure 2. Most Common Reported Impacts Across Domains (N = 15)



"I'd be happy to not have to take anything. But… **in the back of my head, I would probably be worried**, like, **what's going to happen? Is it going to progress?** Is it going to be dormant and then come eat me alive? And then come full force, 20 times full?"

"I definitely think that **it would affect my relationship with my boyfriend if I wasn't on medication.** … I also think I might be more timid, I guess, to engage in sex with my boyfriend too"

"I was just going to say just even over to the aspect of not having to chug around or look for a bunch of pills or just when you hear pills, you only think about… **you won't think about your pills as much because I don't take them like that.** You now suppose you hear a pill jar shaking, you automatically think about your pills."

"At work, I feel it – it depends on whether how well it is acting, and how it changes my symptoms, right? **So, if I don't have fatigue and everything and if I get my concentration back and I think that is good**."

"I would just be happy to have any type of normalcy or closeness to… what I once had. And that would be **me being able to work out – regularly work out, be fitness-prone**, …[to] go out, **maybe go out dancing or go hang out with friends.** I miss hanging out with my friends."

References:
1. Margolis DM, Deeks SG. *J Infect Dis*. 2019;220(suppl 1):S24-6.
2. Lau JSY, et al. *J Infect Dis*. 2022;226:236-45.

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