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Experiences and expectations of participants completing an HIV cure focused clinical trial

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The expectations of the eventual outcomes of HIV cure research potentially differ between investigators and people living with HIV (PLHIV) [1]. Understanding expectations and experiences of PLHIV participating in ‘cure-focused’ clinical trials, particularly the risks of participation, will improve the design of future studies and the process of informed consent. This is particularly important as intervention studies do not deliver immediate clinical benefit, so participant involvement is often altruistic [2], and current studies are also not intended to cure or eradicate HIV; so they are subject to the ‘curative misconception’ [3]. It is therefore critical that investigators leading cure-related trials become aware of the information that participants may need and what participants perceive as acceptable risks [4]. In this study, we surveyed participants to understand their experiences of a cure-focused clinical trial and their general expectations of this field of research.

Participants were adults receiving antiretroviral therapy (ART) who had completed a clinical trial examining the effects of 14 days of the histone deacetylase inhibitor (HDACi), vorinostat, on HIV latency [5]. This was an intensive study requiring frequent blood sampling and rectal biopsies. At the time of initial recruitment to this study in January 2010, this was the first trial to examine repeated doses of an HDACi in PLHIV, and it was unknown whether there could be short-term adverse effects from the medication, activation of replication of HIV or other viruses, or the potential for HIV virological failure. The long-term effects of HDACi still remain largely unknown.

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Conflicts of interest

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To examine the expectations of participants before entering the study and the experiences after study completion, a survey was administered. Survey items focused on the experiences and satisfaction with trial participation and the desirability of two potential HIV cure scenarios. The first scenario considered was the desirability of a ‘sterilizing cure’ which was described as being completely cured with the ability to stop ART and no need for further visits to the doctor for HIV care. The second scenario enquired about the desirability of a ‘functional cure’ or remission, where HIV was still present, doctor visits to monitor HIV were still required, but ART could be ceased. We also asked participants to rank the importance of five potential benefits of HIV cure: stopping ART, stopping doctor visits, not being able to transmit HIV, unable to be reinfected with HIV, and being considered as someone not infected with HIV. Importantly, survey items did not focus on how this clinical trial might cure HIV as this was not the objective of the trial. Scenarios were compared by Wilcoxon signed-rank (sterilizing versus functional cure) and Kruskal–Wallis (five potential benefits) tests.

All 20 participants completing the clinical trial also completed the survey. Participants expressed high levels of satisfaction with the study and would consider future studies. When using a scale of 0–100, median satisfaction with the overall study experience was 90 (interquartile range 85–95), 85% of patients would consider enrolling in a similar study focused on HIV cure if approached, whereas 30% acknowledged concerns about vorinostat impacting their health at study entry. When considering possible cure scenarios, 90% rated a ‘sterilizing cure’ very desirable compared to 55% for a ‘functional cure’ ($P = 0.02$). When ranking five potential benefits of cure, greatest importance was placed on stopping HIV transmission (47% ‘most important’) and least importance on stopping doctor visits to monitor HIV (0% ‘most important’) ($P < 0.01$ when comparing all five scenarios) (Table 1).

High levels of participant satisfaction were achieved during an intensive clinical trial focusing on HIV cure. A sterilizing HIV cure was viewed as more desirable than a functional cure, and the potential benefit of not transmitting HIV was considered most important. Currently, there is a scarcity of data on community expectations of HIV cure research, which is surprising, considering the large number of clinical trials currently underway or scheduled to commence in this field [6]. The high priority on blocking HIV transmission was interesting as this is rarely considered in the rationale for the cure agenda [7] or cure-related studies – given the efficacy of current ART in blocking transmission [8]. These results will allow researchers to more accurately inform participants about the long-term rationale for current studies and more clearly discuss potential cure scenarios, including whether alternate terms such as ‘remission’ may be more appropriate than ‘cure’ in the context of currently available data [4,9]. A broad approach engaging both the general media to enable clear interpretation of results of similar studies [10] and active community engagement is essential to understand and manage expectations of PLHIV in this growing and important field of HIV research.

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Participant expectations on completing an intensive HIV cure focused clinical trial.

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