

## New study confirms the existence of 'trial effect' in HIV clinical trials

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A new study by investigators from the University of North Carolina at Chapel Hill School of Medicine has confirmed the existence of a "trial effect" in clinical trials for treatment of HIV.

Trial effect is an umbrella term for the benefit experienced by [study participants](#) simply by virtue of their participating in the trial. It includes the benefit of newer and more effective treatments, the way those treatments are delivered, increased care and follow-up, and the patient's own [behavior change](#) as a result of being under observation.

"Trial effect is notoriously difficult to test," said Prema Menezes, PhD, assistant professor of medicine at UNC and lead author of the study.

"Our study used the objective finding of [viral load](#) to test our hypothesis," she said.

Researchers compared [viral suppression](#) among patients who began highly [active antiretroviral therapy](#) (HAART) in a clinical trial with patients who received HAART in routine clinical care in two different time periods, 1996-1999 and 2000-2006. They found clear evidence of a trial effect during the earlier period, but not during the later period. Researchers offer that improvements to antiretroviral therapy (fewer pills and fewer side effects), and the change in attitude to HIV, which has come to be seen by many as a chronic, but treatable infection, may be among the explanations for the lack of demonstrable trial effect in the later period.

"This is the first study to clearly demonstrate a trial effect in HIV [clinical trials](#), and this has important implications moving forward," Menezes said. Documentation of a clinical trial effect should be considered when interpreting the generalizability of clinical trial results. At the same time, the fact that no trial effect was observed in the current HAART period argues that the efficacy demonstrated in clinical trials is likely to predict the effectiveness of the therapy in broader treatment populations. Clinicians and public health officials may have increased confidence that treatment guidelines based on clinical trial data are relevant to routine clinical care.

**More information:** Menezes P, Miller WC, Wohl DA, Adimora AA, Leone PA, et al. (2011) Does HAART Efficacy Translate to Effectiveness? Evidence for a Trial Effect. PLoS ONE 6(7): e21824. [doi:10.1371/journal.pone.0021824](https://doi.org/10.1371/journal.pone.0021824)

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