rm efficacy of modified directly observed antiretroviral treatment in Mombasa, Kenya: a randomized trial

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Abstract:

Objectives:To determine short- and long-term efficacy of modified directly observed therapy (m-DOT) on antiretroviral adherence. Design:Randomized controlled trial. SETTING AND ANALYTIC APPROACH: From September 2003 to November 2004, 234 HIV-infected adults were assigned m-DOT (24 weeks of twice weekly health center visits for nurse-observed pill ingestion, adherence support, and medication collection) or standard care. Follow-up continued until week 72. Self-reported and pill-count adherence and, secondarily, viral suppression and body mass index measures are reported. Generalized estimating equations adjusted for intraclient clustering and covariates were used. Results:During weeks 1-24, 9.1% (9/99) of m-DOT participants reported missing doses compared with 19.1% (20/105) of controls (P = 0.04) and 96.5% (517/571) of m-DOT pill-count measures were >or=95% compared with 86.1% (445/517) in controls [adjusted odds ratio = 4.4; 95% confidence interval (CI) = 2.6 to 7.5; P < 0.001. Adherence with m-DOT was 4.8 times greater (95% CI = 2.7 to 8.6; P < 0.001) with adjustment for depression and HIV-related hospitalization. In weeks 25-48, adherence with m-DOT (488/589) was similar to controls (507/630). Viral suppression at 48 weeks was 2.0 times (95% CI = 0.8 to 5.2; P = 0.13) as likely in m-DOT participants as controls. M-DOT patients had larger body mass index increases at 24 weeks (2.2 vs 1.4 kg/m3; P = 0.014). Viral suppression was more likely at week 48 (21/25 vs 13/22; P = 0.057) and week 72 (27/30 vs 15/23; P = 0.027) among depressed participants receiving m-DOT. Conclusions:M-DOT increased adherence, most notably among depressed participants