Evaluation of a combination adherence strategy to support HIV antiretroviral therapy for pregnancy and breastfeeding in Malawi: A pilot randomized clinical trial

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Background

There has been tremendous progress in reducing vertical transmission of HIV in the past two decades due to the broad availability of antiretroviral therapy (ART) in LMICs. Despite this progress, breakthrough paediatric infections are still occurring.

Methodology

In a pilot study, we evaluated a combination adherence support package, which included an adapted motivational interviewing-informed counselling approach (Integrated Next Step Counselling, iNSC) and an optional adherence supporter, for pregnant and breastfeeding women living with HIV. Participants were recruited from the antenatal clinic in Lilongwe, Malawi. Eligible participants were randomly allocated 1:1 to receive either the combination adherence package (intervention) or standard care (control) at the health facility. Our clinical outcome, measured at three- and six-month follow-up, was a composite endpoint of study retention with HIV viral suppression (HIV RNA <40 copies per mL).

Table 1:Component of outcome definition

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Outcome	Time point	n	Intervention	Control	Unadjusted probability difference (95% CI)	Adjusted probability difference (95% CI)^
Retained in care						
	At Month 3	100	46/51 (90.2%)	46/49 (93.9%)	-3.7% (-14.2%, 6.9%)	-1.2% (-12.4%, 10.1%)
	At Month 6	100	41/51 (80.4%)	43/49 (87.8%)	-7.4% (-21.6%, 6.9%)	-5.0% (-19.8%, 9.9%)
Viral suppression (<40 copies/mL)						
	At Month 3	92	36/46 (78.3%)	34/46 (73.9%)	4.3% (-13.1%, 21.8%)	2.6% (-13.4%, 18.6%)
	At Month 6	84	35/41 (85.4%)	30/43 (69.8%)	15.6% (-1.9%, 33.1%)	11.0% (-5.6%, 27.6%)
Retained in care with viral suppression						
	At Month 3	100	36/51 (70.6%)	34/49 (69.4%)	1.2% (-16.8%, 19.2%)	1.1% (-16.2%, 18.4%)
	At Month 6	100	35/51 (68.6%)	30/49 (61.2%)	7.4% (-11.3%, 26.1%)	6.7% (-11.8%, 25.4%)

^ Adjusted for baseline imbalances in Log(10) viral load, gestational age, primary source of income, and number of children

Results

We screened 106 women living with HIV between March and July 2020. Of these, 100 women enrolled and were randomly assigned to intervention (n=51) or control (n=49). The majority of participants (94 of 100; 94%) were newly diagnosed with HIV. Retention in care was 92% at three months and 84% at six months. Three-quarters of women retained in care were virally suppressed at the three- and six-month study visits. At three months, our composite outcome (retention & viral suppression) was achieved by 70.6% (36/51) and 69.4% (30/43) of women in the intervention and control groups, respectively. At six months, this composite outcome was achieved by 68.6% (35/51) of the intervention group and 61.2% (30/49) of the control group (probability difference: 7.4%, 95% CI: -11.3%, 26.1%).

Conclusion

These encouraging pilot findings suggest that this combination adherence package could be used to support ART adherence among pregnant and breastfeeding women living with HIV. We demonstrate feasibility of using a combined measure of adherence and viral suppression as an outcome measure and how this could be enhanced through behavioral strategies.

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