

## Abstract

We previously demonstrated a decrease in bacterial vaginosis (BV) and an increase in Lactobacillus colonization among randomized controlled trial (RCT) participants who received monthly oral periodic presumptive treatment (PPT) [2g metronidazole + 150mg fluconazole]. Post-trial data were analyzed to test the hypothesis that the treatment effect would persist following completion of one year of PPT.

**Methods** Data were obtained from women who completed all 12 RCT visits and attended  $\geq 1$  post-trial visit within 120 days following completion of the RCT. We used Andersen-Gill proportional hazards models to estimate the post-trial effect of the intervention on the incidence of BV by Gram stain and detection of Lactobacillus species by culture.

**Results** The analysis included 165 subjects (83 active and 82 placebo). The post-trial incidence of BV was 260 per 100 person-years in the intervention arm versus 358 per 100 person-years in the placebo arm (hazard ratio [HR]=0.76; 95% confidence interval [CI]: 0.51–1.12). The post-trial incidence of Lactobacillus colonization was 180 per 100 person-years in the intervention arm versus 127 per 100 person-years in the placebo arm (HR=1.42; 95% CI: 0.85–2.71).

**Conclusions** Despite a decrease in BV and an increase in Lactobacillus colonization during the RCT, the effect of PPT was not sustained at the same level following cessation of the intervention. New interventions that reduce BV recurrence and promote Lactobacillus colonization without the need for ongoing treatment are needed.