

## **The HAART cell phone adherence trial (WeITel Kenya1): a randomized controlled trial protocol.**

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Date: 2009-09

### **Abstract:**

**BACKGROUND:** The objectives are to compare the effectiveness of cell phone-supported SMS messaging to standard care on adherence, quality of life, retention, and mortality in a population receiving antiretroviral therapy (ART) in Nairobi, Kenya. **METHODS AND DESIGN:** A multi-site randomized controlled open-label trial. A central randomization centre provided opaque envelopes to allocate treatments. Patients initiating ART at three comprehensive care clinics in Kenya will be randomized to receive either a structured weekly SMS ('short message system' or text message) slogan (the intervention) or current standard of care support mechanisms alone (the control). Our hypothesis is that using a structured mobile phone protocol to keep in touch with patients will improve adherence to ART and other patient outcomes. Participants are evaluated at baseline, and then at six and twelve months after initiating ART. The care providers keep a weekly study log of all phone based communications with study participants. Primary outcomes are self-reported adherence to ART and suppression of HIV viral load at twelve months scheduled follow-up. Secondary outcomes are improvements in health, quality of life, social and economic factors, and retention on ART. Primary analysis is by 'intention-to-treat'. Sensitivity analysis will be used to assess per-protocol effects. Analysis of covariates will be undertaken to determine factors that contribute or deter from expected and determined outcomes