

WELTEL RETAIN: A RANDOMIZED CONTROLLED TRIAL PROTOCOL OF A TEXT-MESSAGING INTERVENTION TO IMPROVE PATIENT RETENTION IN PRE-ANTIRETROVIRAL THERAPY HIV CARE

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ABSTRACT

High levels of patient retention after first clinical contact contribute to the timely initiation of antiretroviral therapy (ART) and better health outcomes. In Kenya (WelTel Kenya1), a weekly short message service (SMS) text message led to improved ART adherence and viral load suppression.

The objectives of this study are to: 1) determine if the WelTel intervention improves retention in Stage 1 HIV care (patient receives CD4 count results); 2) determine whether the WelTel intervention improves 12-month retention; and 3) evaluate the cost-effectiveness of the WelTel intervention.

A randomized controlled trial will be conducted at the Kibera Community Health Centre in Nairobi, Kenya. Over one year, HIV positive individuals newly enrolling at the clinic will be recruited and randomly allocated to an intervention or control arm (standard care) at a 1:1 ratio. Intervention arm participants will receive a weekly SMS 'check-in' to which they will be required to respond within 48 hours. An HIV clinician will follow-up and triage any problems that are identified. Patients will be followed for one year, with a primary endpoint of retention in care at 12 months.

This study is in a pre-enrolment phase; a recruitment target of 686 participants provides 80% power to detect a proportionate difference of 15% in the primary outcome ($\alpha=0.05$). Data will be analyzed according to intention to treat principles. Chi-squared tests will be used for categorical outcomes; and t-tests or Mann-Whitney U tests for continuous outcomes.

The WelTel Retain trial will contribute important information on the effectiveness of an established mHealth intervention to engage patients in care during the first year of HIV care, before initiating ART. Trial results and cost-effectiveness evaluation will inform how WelTel might contribute to the long-term success of PEPFAR-funded programs and towards a sustainable global HIV/AIDS response