

Trial number: NCT03086655

Tel-Me-Box:

Testing a New, Real-time Strategies for Monitoring HIV Medication Adherence in India

Statistical analyses Plan:

This is a feasibility trial of automated reminders from an electronic pillbox (the Tel-Me-Box). Feasibility analyses will include tabulation of preference for the different kinds of reminder available. Further descriptive analyses will include calculation of enrollment and retention rates over the 12-month follow-up period.

To assess if tailored real-time adherence feedback via Tel-Me-Box shows potential to improve adherence, we will compare adherence from Tel-Me-Box (quarterly assessment for 12 months), as well as HIV viral loads, and hair ARV levels (both every 6 months) in the intervention (Tel-Me-Box with reminder) and control groups (Tel-Me-Box without a reminder). We will also compare self-reported adherence (assessed quarterly) between the 2 arms. Differences between the two groups in change in the outcomes over time will be assessed via the interaction between time and group in GEE linear or logistic regression models, for continuous and categorical versions of the outcome variables, respectively. Count variables will be analyzed via Poisson or negative binomial regression, depending on absence (Poisson) or presence (negative binomial) of overdispersion in the data distribution. Robust standard errors will be used in cases of deviation from normality in the linear regression models. *Note that these analyses are for illustration purposes only, as these were not the primary analyses this pilot study was powered for.*