Tel-Me-Box: Validating and testing a novel, low cost, real-time monitoring device with hair level analysis among adherence-challenged patients

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Project Description

"Tel-Me-Box" is a small, low-cost, adherence monitoring device, developed by our team that transmits a wireless signal to a server when opened. Since it cannot assess actual drug ingestion, validation against a biological measure of adherence is crucial. The overarching hypothesis of this application is that adherence data captured by Tel-Me-Box will demonstrate strong relationships with an objective biomarker of adherence (i.e. hair concentrations of ARVs) and predict virologic suppression in treated HIV-infected individuals. We additionally hypothesize that tailored real-time adherence feedback via this device will improve adherence rates to HIV therapy for adherence-challenged patients in a pilot randomized clinical trial. This five-year study is being conducted in collaboration with our colleagues at St. John's National Academy of Health Sciences in Bangalore and the Karnataka State government.

Specific objectives include:

Aim 1 will refine Tel-Me-Box by adding tailored reminder features. We will also demonstrate feasibility of hair analysis in RLS by training local staff to conduct the relevant hair assays.

Aim 2 will validate the Tel-Me-Box adherence measure, using ARV hair concentrations and HIV viral load, and examine the predictive utility of Tel-Me-Box monitoring and hair drug levels on virologic suppression in HIV-infected patients.

Aim 3, will conduct a pilot RCT to examine acceptability and feasibility and estimate the effect size of automated tailored real-time adherence reminders on hair ARV concentrations, device-monitored adherence, and viral load suppression in adherence-challenged patients.

Significance

Novel, validated methods to monitor adherence to HIV treatment in real time are urgently needed given the well-known limitations of self-reported adherence, pill counts, and medication electronic monitoring system caps. In order to be scalable and sustainable in LMICs, such devices need to be low-cost and designed in a way that does not increase the risk of accidental HIV disclosure and subsequent stigma. Devices which both monitor adherence in real time and provide tailored reminders to patients for medication-taking have the potential to greatly improve adherence to HIV treatment as well as to treatment for other chronic diseases. **Project End Date**: June, 2021