In resource limited settings, digital adherence technologies that are feature-phone based have the potential to facilitate patient-centric approaches to treatment and care delivery, while providing HCWs with real-time data that can enable effective patient triage.22

**Primary Objective:** We are undertaking a randomized control trial (RCT) at two sites (Infectious Disease Institute [IDI] & Kasangati HIV KISG), designed to optimize adherence, virologic outcomes and HIV knowledge, to provide an overall increased quality of life in vulnerable populations starting or already on ART in Kampala, Uganda.

**Methods**

This study is an open label RCT at 2 sites: IDI which is an urban centre of excellence in HIV care & KISG, a peri-urban, public health care facility. The estimated length of the study is 30 months; participants seen at baseline, months 0, 6, 12 & 24. The technology evaluated in this study is Connect for Life™ mHealth technology (Gisson, JKI) in comparison to standard of care (SoC). This has been adapted to the Ugandan setting by IDI and termed Call for Life Uganda (CFLU). CFLU allows a patient to interact with patients through the use of voice and text input via keypad (IVR) or text message (SMS). The interventions include pill reminders, clinic visit reminders, health tips and functionality to support symptom reporting in addition to SoC. Control arm included only SoC (Figure 1).

The primary end point was change in quality of life physical health score (QOL-PHS) among patients accessing Call for Life Uganda™ between baseline, 6, 12 and 24 months of Call for Life Uganda™ use, and comparison to those with no access to Call for Life Uganda™ at same time points. Analysis of QOL was done using the MOS-HIV survey, validated for use in HIV patients in Uganda. Secondary endpoints included comparison in change in QOL mental health score (QOL-MHS), overall QOL score and viral load between arms. Qualitative data was collected using focus group discussions and in depth interviews of participants and HCWs between baseline and 6-12 month points at study close out.

MOS-HIV has 11 scales and uses a Likert type dichotomous scoring. We used difference in difference (DID) with Chi square and Fishers exact test. ANCOVA analysis was also performed.

Full ethical approval was obtained from Makerere School of Public Health and Uganda National Council of Science and Technology (UNCAST).

**Results**

1013 participants were screened at the 2 sites with 796 being eligible and 600 were enrolled (n=300/line) as shown in figure 2 above. Sixty-nine percent were female and median age was 32 (IQR25-40). Eighty four participants were ART naïve, taking ART for the first time. At baseline, 97% chose IBM over SMS, (Table 1)

6 month results 277 in each arm attended at 6m. There is no statistical observed difference in mean percentage of those who were switched to second line ART or switching to second line, there was a significant improvement in MOS-VLS (ANCOVA 4.01, p=0.048). There was no significant difference between CFLU versus the SoC in the proportion of patients with viral load <50 copies at 6m (21% vs 18%; p-value=0.372).

Qualitative analysis at baseline and 6-12months revealed that in general participants have positive reports about the tool. Pill reminders and health information tips were the most valued functions.

Challenges of the study included participant level – forgetting pin codes, frequent phone number changes. Technical issues include mobile network malfunctions, power outages, and sporadic system downtimes.

**Discussion**

This is the first RCT for ART adherence incorporating options for IVR and SMS options as well as symptom reporting and health tips. At 6 month analysis, we have not seen a statistically significant difference between the 2 arms of this study based on primary outcome of QOL-PHS. Secondary outcomes of MOS-MH, MOS-total and viral load have also not shown differences. This may be due to the higher than expected baseline QOL and virologic suppression in the populations we studied, leading to insufficient power to show a difference in the 6 months.

However, CFLU did show a significant effect on HIV adherence and first line ART failing patients who were switching to second line. Furthermore, qualitative data suggests a high acceptance and positive experiences with the CFLU tool in PVHU. Another interesting finding is the almost total selection of interactive voice response over text messages.

Analysis of the 12 month data, tool usage data, effect on sexual behavior, willingness to pay for the tool post study and full qualitative analysis is ongoing.