Call for Life Uganda ™: An RCT using interactive voice response for PLHIV on ART

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Introduction

In resource limited settings, digital adherence technologies that are feature-phone based have the potential to facilitate patient-centric approaches to transform HIV care delivery, while providing HCPs with real-time data that can enable effective patient triage[1,2].

Primary Objective: We are undertaking a randomized control trial (RCT) at two sites (Infectious Diseases Institute (IDI) & Kasangati HCIV (KSG), designed to optimize adherence, virologic outcomes and HIV knowledge, to provide an overall increased quality of life in vulnerable populations starting or established 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 & KSG, a peri-urban, public health care facility. The estimated length of the study is 30 months; participants seen at baseline, months 06,12,18 & 24.

The technology evaluated in this study is Connect for Life™ mHealth technology (Janssen, J&J) 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 computer to interact with patients through the use of voice and tone input via keypad (IVR) or by 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).

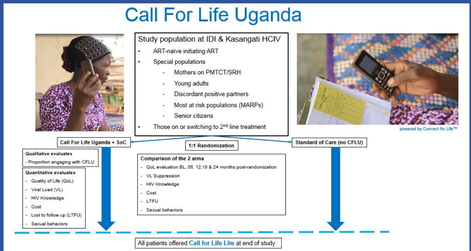
The primary end point was change in quality of life physical health score (QOL-PHS) among patients accessing Call for Life Uganda™ between baseline, 6, 12 and 24 months of Call for Life Uganda™ use, and comparison to those with no access to Call for Life Uganda™ at same time points. Analysis of QOL was done using the MOS-HIV survey, validated for use in HIV patients in Uganda [3]. Secondary end points 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 HCP between baseline – 6 months, 6-12 months and 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 (UNCST).

FIGURE 1. Study Schema



Acknowledgements
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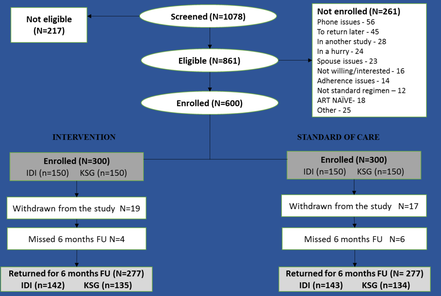
Results

Figure 2. Consort Diagram for study



1013 participants were screened at the 2 sites with 796 being eligible and 600 were enrolled (n=300/site) as shown in figure 2 above. Sixty-nine percent were female and median age was 32 (IQR25-40). Eighty four participants were ART naïve, remaining ART experienced. **At baseline, 97% chose IVR over SMS.** (table 1)

Table 1. Baseline Characteristics of study participants

Characteristic	Total	ARM n (%)		P-value	Site n (%)		P-value
	(N=600)	Intervention (N=300)	Standard (N=300)		IDI (N=300)	KSG (N=300)	
Gender							
Female	413(68.8)	210(70.0)	203(67.7)	0.537	171(57.0)	242(80.7)	0.000
Male	187(31.2)	90(30.0)	97(32.3)		129(43.0)	58(19.3)	
Age in complete years							
16-24	161(26.8)	82(27.3)	79(26.3)	0.782	53(17.7)	108(36.0)	0.000
25-35	219(36.5)	104(34.7)	115(38.3)		91(30.0)	128(42.7)	
36-50	181(30.2)	95(31.7)	86(28.7)		124(41.3)	57(19.0)	
≥ 50	39(6.5)	19(6.3)	20(6.7)		32(10.7)	7(2.3)	
Marital Status							
Married	449(74.8)	223(74.3)	226(75.3)	0.778	219(73.0)	230(76.7)	0.301
Not Married	151(25.2)	77(25.7)	74(24.7)		81(27.0)	70(23.3)	
Education level							
None	24(4.0)	8(2.7)	16(5.3)	0.317	12(4.0)	12(4.0)	0.000
Primary	231(38.5)	118(39.3)	113(37.7)		103(34.3)	128(42.7)	
Secondary	265(44.2)	137(45.7)	128(42.7)		124(41.4)	141(47.0)	
Tertiary	80(13.3)	37(12.3)	43(14.3)		61(20.3)	19(6.3)	
Employment Status							
Employed	417(69.5)	203(67.7)	214(71.3)	0.329	235(78.3)	182(60.7)	0.000
Not employed	183(30.5)	97(32.3)	86(28.7)		65(21.7)	118(39.3)	
Alcohol use							
Yes	292(48.7)	147(49.3)	144(48.0)	0.744	150(50.0)	142(47.3)	0.513
No	308(51.3)	152(50.7)	156(52.0)		150(50.0)	158(52.7)	
Prior TB diagnosis							
Yes	87(14.5)	42(14.0)	45(15.0)	0.728	72(24.0)	15(5.0)	0.000
No	513(85.5)	258(86.0)	255(85.0)		228(76.0)	285(95.0)	

Table 2. Mean percentage scores of MOS-HIV, MHS & PHS by Arm & Site: Baseline to month 6 follow up

Outcome variable	BASE LINE		FOLLOW UP		ANCOVA ANALYSIS	
	I (Mean)	S (Mean)	I (Mean)	S (Mean)	F-value	p-value
MOS-HIV						
Over all	85.5	85.6	88.5	88.7	0.18	0.669
IDI	89.3	90.5	90.7	91.6	0.76	0.383
KSG	81.4	80.1	86.2	85.7	0.00	0.997
MHS						
Over all	86.4	86.7	90.1	89.8	0.48	0.488
IDI	90.8	91.8	92.4	93.1	0.87	0.353
KSG	81.7	81.3	87.6	86.3	1.90	0.169
PHS						
Over all	86.7	86.8	90.2	90.9	0.87	0.351
IDI	90.2	91.8	92.3	93.5	0.50	0.481
KSG	82.9	81.3	87.9	88.1	0.45	0.501

6 month results 277 in each arm attended at 6m. There is no statistical observed difference in mean percentage score of MOS-HIV, MHS and PHS at baseline and 6m between CFLU and SoC arms**. In those starting first line ART or switching to second line, there was a significant improvement in PHS (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 [4] and 6-12months revealed that in general participants responded positively 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.

"I also just want to praise it because it has done a lot for me. Ever since I joined CFL, I have perfect adherence to my ARVS unlike before when I was reluctant to take my drugs. I think I was just lazy and I had poor adherence. But ever since I joined CFL I take my pills on time." (IDI participant, FGD).

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 the RCT study based on primary outcome of QOL-PHS. Secondary outcomes of MOS-MH, MOS-overall and viral load have also not shown differences. This may be due to the higher than expected baseline QOL and virological suppression in the populations we studied, leading to insufficient power to show a difference in the arms.

However, CFLU did show a significant effect on PHS in ART-naïve 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 PLHIV. 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.

Conclusion

This study demonstrates that people living with HIV (PLHIV) will accept, utilize and are positive about CFLU services, which provide pill and visit reminders, health tips with information on HIV and the 2-way communication between patient and the clinic for symptom and psychologic support. Patient preference is strong for IVR over SMS. All types of participant were positive about C4LU, but effect on QOL-PHS is statistically significant in those starting or switching ART.

References 1. Campbell A.R., et al., 2018.. *JMIR mHealth and uHealth*. 6(7): p. e152-e152.
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3.Mast et al. AIDS Care 16(1):81-94
4.Twimukye A et al Exploring Attitudes and Perceptions of Patients and Staff Towards "Call for Life" System for HIV Antiretroviral Therapy in Uganda: A Qualitative Study. Cote D'Ivoire: International Conference on AIDS & STIs in Africa (ICASA); 2018. Poster number A-918-0002-01426.