Family Clinic Day RCT in Uganda: Child Antiretroviral Therapy Retention and Adherence

Justin C Graves[1], Christine J Schellack[2], Margaret L Prust[1], Esther Mirembe[2], Marta R Prescott[1], Betty Mirembe[2], Ivan Lukabwe[3], Barbara Asire[3], Peter Elyanu[3], Sarah A Moberley[2]

[1]Clinton Health Access Initiative, USA, [2] Clinton Health Access Initiative, Uganda, [3]AIDS Control Program, Uganda Ministry of Health

CROI 2016 BOSTON

Poster 844

BACKGROUND

New policies and low retention rates could pose issues for the antiretroviral therapy (ART) program in Uganda

Uganda recently adopted a test-and-treat policy for HIV patients 15 years or younger. This change in guideline was estimated to increase the number of children and adolescents on ART by 50% in one year, from 43,524 to 64,524 patients.[1] However, low 12 month ART retention rates (78.7%) [2,3] among children and adolescents may threaten their adherence to treatment and pose a risk of early treatment failure.

The Uganda Ministry of Health recommended developing evidence-based interventions to improve retention and adherence of patients on ART. Although family-centred care models have been implemented in Uganda and have shown anecdotal evidence of positive impact on ART care, [4,5] to date there is limited evidence regarding their impact on retention and adherence, especially among children and adolescents.

This study aimed to measure the impact a family clinic day care model on retention and ART adherence among children and adolescents in Uganda

OBJECTIVES

Primary objectives

Among pediatric and adolescents, to determine whether the FCD was able to:

1. Improve retention in care
2. Improve adherent to their clinic appointment schedule.



Secondary objective

Among non-FCD eligible HIV infected adults, to determine whether the intervention:

1. Changed retention in care
2. Changed adherence to their clinic appointment schedule

FAMILY CLINIC DAY INTERVENTION

Family Clinic Day (FCD) is a facility-based appointment scheduling and health education intervention that prioritizes the needs of pediatric and adolescent ART patients and their families

1. ***Patient scheduling:*** The FCD model provides appointment scheduling on regularly-occurring, designated family clinic days that prioritize children, adolescents, and their HIV positive family members. Proactive identification of patients and their families reroute them to FCD using a reminder card system.
3. ***Health education***: Specialized health education sessions conducted during FCD with adolescents and caregivers, regarding HIV basics and background, adherence, disclosure, puberty, sexual and reproductive health, and life skills among other topics.
5. ***Patient flow***: While no patient will ever be refused care, children, adolescents, and their families will be seen first over other patients during designated FCDs.

METHODS

Study Design

This study was a clustered randomized controlled trial. Forty-six facilities with ≥30 patients aged 15 years or younger who were active in pre-ART or ART were stratified by implementing partner and facility type, and randomized to the control or the intervention arm.

The training included a two-step cascade supplemented by mentorship supervision to ensure the quality of the intervention. The FCD was implemented for 6 months beginning on 1 October 2014 and ending on 31 March 2015

Outcomes

Retention: Eligible if patients were active in care at any point in the study and were classified as retained in care if they visited the ART clinic at least once in the 3 months before the end of the study. Any patients transferred out were excluded.

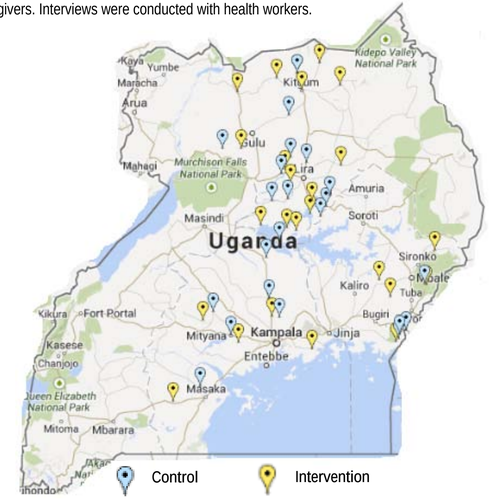
Adherence to appointment: If they returned to the clinic for their most recent appointment in a number of days that was equal to or less than the number of ARV pills prescribed at their last appointment.

Data Analysis

Generalized Estimation Equation Regression: Crude and adjusted odds ratios were used to compare retention and adherence across arms at the individual level. The adjusted GEE regression models reported for retention and adherence controlled for ART initiation category, age, region, gender, ART representation and facility level.

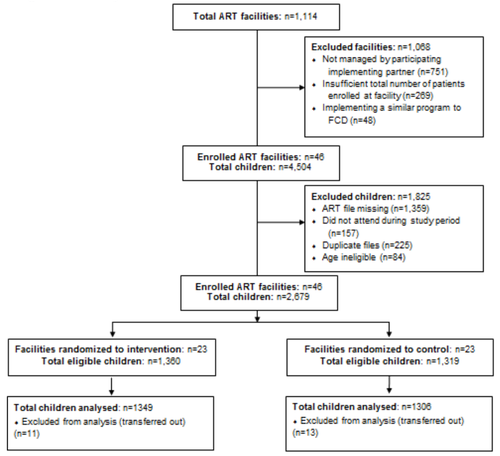
Non-inferiority: The FCD-ineligible adult patient population not receiving ART care as part of a family unit were tested for non-inferiority by using predicted probability from the GEE model to assess whether adjusted retention did not drop below seven percentage points.

Focus Group Discussions: Used to explore perspectives on FCD implementation and to better understand the facility-level experience, and were aimed at adolescent patients and caregivers. Interviews were conducted with health workers.



RESULTS

Figure 1: Study flow chart



Characteristics	Control (n=1319)	Intervention (n=1360)	P-value
Initiation category			0·49
Within past 3 months	137 (6·0%)	166 (7·2%)	
4-11 months	739 (32·6%)	660 (28·7%)	
12-24 months	368 (16·2%)	355 (15·4%)	
More than 24 months	1023 (45·1%)	1121 (48·7%)	
Age			0·50
19-23 months	14 (0·6%)	6 (0·3%)	
2-4 years	408 (17·6%)	419 (17·8%)	
5-9 years	991 (42·8%)	1114 (47·3%)	
10-15 years	647 (27·9%)	581 (24·7%)	
16-19 years	256 (11·1%)	236 (10·0%)	
Region			0·69
Central 1 & 2	630 (26·4%)	350 (14·7%)	
Mid-Eastern	385 (16·1%)	357 (15·0%)	
Mid-Northern	1370 (57·4%)	1669 (70·3%)	
Gender			0·74
Male	972 (43·1%)	908 (42·0%)	
Female	1284 (56·9%)	1256 (58·0%)	
Ever Represented*			0·68
Yes	1382 (42·0%)	1299 (45·3%)	
No	1002 (58·0%)	1077 (54·7%)	
Facility Level			0·63
Hospital	497 (20·8%)	768 (32·3%)	
Health Center III	1378 (57·8%)	935 (39·3%)	
Health Center IV	510 (21·2%)	673 (28·3%)	

Data presented are n(%). *Ever represented is a measure of whether a child was represented by a caregiver at any point during the period instead of attending the clinic in person

Table 1: **Weighted characteristics of child and adolescent patients by treatment arm**

Figure 2: Pediatric and adolescent odds ratio of retention and adherence

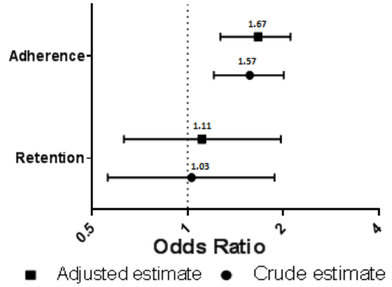
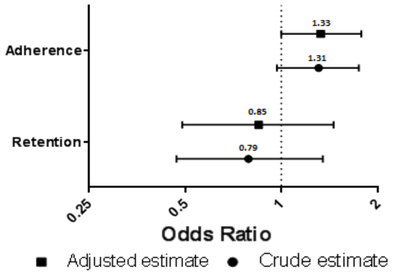


Figure 3: Adult odds ratio of retention and adherence



Among pediatric and adolescent patients, FCD increased adherence to appointment schedule, but retention was not affected

Overall, 92% (n=2166) from the intervention group and 91% (n=2148) from the control group were retained in care at the end of the study period. Patients enrolled in care at an intervention facility had an 11% higher odds of being retained in care as compared to that of control facilities (Figure 2), however the difference was not significant (90% CI 0·63 − 1·97, p value 0.75).

Findings indicated 65.5% from the intervention facilities were adherent to their appointment schedule compared to 55.3% of participants from control sites. (Figure 2) (aOR 1·67; 90% CI 1·27−2·11, p value <0·01).

FCD intervention had no effect on non-FCD adult retention or adherence

Overalll, 91.9% (n=1016) from the intervention group and 93.4% (n=1159) from the control group were retained in care at the end of the study period. Patients enrolled in care at an intervention site were 15% less likely to be retained in ART care than participants from control facilities (Figure 3), however this was not significant (aOR 0.85; 90% CI 0·49−1·46, p value 0·62). There was no difference in adjusted adherence to appointment schedule between control (74.5%) and intervention (78.6%) (aOR 1·33; 90% CI 1·00 − 1·78, p value 0·11).

Adults ineligible for FCD who were attending intervention facilities did not have inferior retention

The adjusted difference in the proportions of retention between the treatment and intervention arms of -0·01 (-0·01 to -0·006); the confidence interval did not reach the threshold of a -0·07% difference.

Qualitative findings suggested the FCD positively influenced the well-being and clinical experience of the children, adolescents, and their families

Participants said the FCD program 1) improved their learning from routine and relevant health education sessions; 2) reduced clinic congestion and waiting time through enhanced appointment system and patient record filing systems; and 3) increased social support within families and peer networks.

CONCLUSIONS

In addition to improving knowledge, reducing clinic congestion and increasing social support, the FCD model improves pediatric and adolescent appointment keeping precisoin – attending the clinic on the exact day that patients were schedule to return. However it does not significantly improve retention.

The Uganda MOH could implement FCD in order to improve patient appointment precision and enhance their clinic experience. These factors may lead to improved patient outcomes.

LITERATURE CITED

1. Monitoring and Evaluation of the Emergency Plan Progress (MEEPP) dataset, September 2013
2. STD/AIDS Control Programme MoH. Status of Antiretroviral Therapy Service Delivery in Uganda, Quarterly Report for March – June 2010, 2010
3. Lukabwe I. STD/AIDS Control Programme, Ministry of Health, Uganda., 2013
4. Luyrika, E., et al., Scaling Up Paediatric HIV Care with an Integrated, Family-Centred Approach: An Observational Case Study from Uganda. PLoS ONE, 2013. 8(8).
5. Musime, V., et al. An adolescent peer support group improves adherence to antiretroviral therapy and reduces self stigma among HIV infected adolescents at joint clinical research centre, Kampala. in 4th IAS Conference on HIV Pathogenesis, Treatment and Prevention: Abstract no. CDB446. 2007. Sydney, Australia.