EFFECT OF FAMILY SUPPORT GROUPS ON RETENTION AMONG HIV+ WOMEN INITIATING LIFELONG ANTIRETROVIRAL TREATMENT (ART) THROUGH PMTCT PROGRAMMES (OPTION B+) AT EGPAF-SUPPORTED HEALTH FACILITIES IN UGANDA

RESEARCH AND EVALUATION REPORT

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Foreword

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List of Acronyms and Abbreviations

ANC:	Antenatal care
ARV:	Anti-retroviral (prophylaxis)
ART:	Anti-retroviral therapy
CD4:	Cluster of differentiation 4; refers to immune cells
CTX:	Cotrimoxazole
DNA:	Deoxyribonucleic acid
DOB:	Date of birth
DPT:	Diphtheria, pertussis, tetanus
EDD:	Estimated date of delivery
EGPAF:	Elizabeth Glaser Pediatric AIDS Foundation
EID:	Early infant diagnosis
FGD:	Focus group discussions
FSG	Family Support Group
GoU	Government of Uganda
HAART	Highly active antiretroviral therapy
HEI:	HIV exposed infants
ICC	Intracluster correlation coefficient
IRB:	Institutional Review Board
LG	Local Government
LTFU	Lost to follow up
MCH:	Maternal and child health
PMTCT:	Prevention of mother to child transmission (of HIV)
PNC:	Post natal care

Executive Summary

The increasing numbers of PLHIV accessing antiretroviral treatment (ART) in sub-Saharan Africa in the last decade poses a challenge of retention in care. As such, ensuring that people remain in care is critical in attaining the 2nd and 3rd 90 UNAIDS target. A number of strategies, including psycho social support activities have been put in place to address retention in care at facilities supported by Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) in south western Uganda. EGPAF conducted a study to assess the retention in HIV care among HIV positive pregnant and lactating women initiated on lifelong Antiretroviral Treatment (ART) through Prevention of Mother to Child Transmission of HIV (PMTCT) Programs (Option B+) in selected health facilities in south western Uganda.

This was a retrospective cohort of women aged 15-49 years in the PMTCT program who were newly initiated on lifelong ART between March and July 2013 at 16 study health facilities. Data was abstracted on a sample of 1,020 women from women's longitudinal HIV care/ART medical records. Retention in care at 6, 12 and 18 was assessed using appointment keeping method. We compared women who participated in the FSG and those who didn't participate in the FSGs. Clinical and demographic factors associated with FSG participation were assessed using existing medical record data. Data analysis was performed using STATA version 14.2.

Out of 1,012 records reviewed, 55% participated in the FSG. The mean age of participants was 26 years (IQR=22-29), most were married (84.2%) while one out of five had an HIV-positive family member. The majority of women (95.9%) were on the recommended national first line ARV regimen, TDF-3TC-EFV. Most study participants did not have a homebased care provider (83.5%) or belonged to an ARV support group (90.7%). A significant proportion (83.1%) had a treatment supporter. Overall, demographic and clinical factors for women enrolled or not enrolled in the FSG were somewhat the same. A significantly greater proportion of FSG participants had a home-based care provider (19.7%) compared to women who did not participate in the FSG (12.5%). We observed significant differences between women who participated and those who did not participate in the FSG with respect to initial CD4 count, with a smaller proportion of FSG participants initiating care with a CD4 count <200 cells/µ (4.9%) and a higher proportion (13.9%) of non FSG participants initiating care with a CD4 count <200 cells/µ.A higher proportion of women did not have a documented initial CD4 count in their medical records (42.8%).

Overall, retention of women in care was higher at 84.2% at 6 months follow up and dropped gradually 67.8% at 18-months follow-up. There was observed variations in retention of women who participated in the FSGs and those who didn't participate in the FSG at 6 months and 18 months of follow up period, with women enrolled in FSG having a higher retention amongst women who participated in the FSG compared to those who did not enroll in the FSG: 6 months follow up retention:91.7% for women who enrolled in FSG compared to 75.1% for women who did not enroll in the FSG), 12 months follow up retention: 85.8% for women who enrolled in FSG compared to 65.9% for women who did not enroll in the FSG), and at 18 months follow up retention:75.7% for women who enrolled in FSG and 58.1% for women who did not enroll in the FSG. The results further showed a positive dose response relationship between number of FSG visit attendance and retention in care. Factors associated with retention in care included: women with an HIV positive family and age. Women with an HIV positive family member had a 40% reduced hazard of attrition from care, HR =0.6 (95% CI: 0.42-0.86). Women aged 30+years had a 70% reduced chance of attrition from care compared to women aged 15-19 years, when adjusted for remaining covariates such as marital status and Pregnancy status, HR= 0.3 (95% CI: 0.19-0.47). Although the univariate analysis indicated that women who initiated ART while pregnant were at increased risk of lost from care, compared to women who initiated ART while breastfeeding the adjusted model indicated no difference between the two groups

In conclusion, the study established that participation in FSGs has a positive effect on retention in HIV care among women initiating ART through PMTCT. Factors associated with retention in care include age, having an HIV positive family member and initiating on ART while breastfeeding. These findings are important in restructuring FSGs with an aim to optimize their effectiveness for better retention in care. Understanding that FSGs are a critical path through which pregnant and lactating women on ART receive peer and psychological support, a service delivery differentiation of approach based on risk factors including age, pregnancy status and support (where available) from other family members living with HIV is critical in retaining women in HIV care.

1.0 INTRODUCTION AND BACKGROUND

While there has been a steady increase in numbers of people accessing antiretroviral treatment (ART) in sub-Saharan Africa in the last decade, retention in care and treatment has remained a challenge and a priority for PEPFAR-supported countries and implementing partners. The advent of the Prevention of Mother to Child (PMTCT) Option B+ strategy, or ART for life for all women[1] from pregnancy through the breastfeeding period, brought a new wave of challenges in retention in HIV care. In 2013, a study conducted in Malawi indicated that women who started on PMTCT Option B+ during pregnancy were five times more likely to fail to return to the clinics after the initial visit, compared with those who were ART treatment eligible as determined by CD4 count (adjusted OR 5.0, 95% CI 4.2–6.1).[1] In this Malawi study, lost to follow up (LTFU) was highest in pregnant Option B+ patients who began ART at large clinics on the day they were diagnosed with HIV; most losses occurred in the first 3 months of therapy. In another Malawi study, women who were offered ART on the same day they were diagnosed HIV-positive reported feeling overwhelmed with having to cope with the HIV diagnosis, disclosure to their partner or family, and having to initiate lifelong ART.[2]

Retention of mothers on ARVs and in care during pregnancy, labor and delivery and during the breastfeeding period reduces the risk of transmission by decreasing maternal viral load and provides opportunity for infant cotrimoxazole prophylaxis. Temporary treatment lapses are detrimental to PMTCT effectiveness. If ART is interrupted, the resulting viral load rebound may greatly increase the risk of transmission to the infant and disease progression in women.

Option B+ in Uganda The Uganda Ministry of Health (MOH) rolled out PMTCT Option B+ guidelines in Uganda in late 2012 through 2014. Routine programmatic data from 105 EGPAF-supported sites reported a 12-month retention rate of 81% among Option B+ clients in 2013,[3] compared to a 90% 12-month retention rate for adults in the ART program in 2014.[2] The data also indicated that HIV-positive pregnant women who initiated ART in the antenatal period had a retention rate of 78%, compared to 85% for women who initiated ART during the breastfeeding period. Studies in HIV programs elsewhere have also found that initiating ART during pregnancy is a risk factor for poor retention in care.[4] [5]

EGPAF has implemented a number of retention-targeting strategies to improve retention in HIV care, including strategies targeting mother–infant pairs in PMTCT programs. Some examples include active search for clients that miss clinic visits, treatment supporters, home-based care, ARV support groups, family support groups, and peer educators. Routinely collected program data from EGPAF-supported sites showed that sites with family support groups (FSG) were associated with higher average 12-month retention rates at the site level. These findings raised the question of whether participation in FSGs would be associated with retention of women in Option B+, when assessed using patient-level data.

Evidence on support groups to increase retention in HIV care: While several studies have identified support groups as factors associated with retention or self-reported adherence,[6] [7] [8] not all have found such an association.[9] A 2015 systematic review described the quality of the evidence on the effect of support groups on retention in care of PLHIV as *fair*,[10] referring to limitations in study design (eg. no comparison group), small sample sizes, and generalizability of the population studied. Since support groups may differ substantially in structure (eg. location),

[1] PMTCT option in which all pregnant women living with HIV are offered lifelong ART, regardless of their CD4 count. This option was defined in reference to two WHO PMTCT ARV guidance options: (1) Option A (WHO 2006), in which HIV+ women receive antenatal and intrapartum ARV prophylaxis and HIV-exposed infants (HEIs) receive prophylaxis throughout the breastfeeding period, and (2) Option B (WHO 2010), in which women all receive triple therapy from antenatal through the breastfeeding period but only continue triple therapy thereafter when they are eligible as determined by CD4 count and clinical staging (defined at country level).

[2] At the national level, 12-month retention in ART in Uganda in 2013 was reported at 84% among adults.

operation (eg. facilitation, frequency of meetings, content etc), and target population (ie. eligibility criteria), one might expect variation in effectiveness.

There are fewer studies looking at support group models that include family members. A 2015 study[11] in Kenya found that participants of microclinics, or groups of close family, friends or other members of the patient's social support system, experienced half the rate of >= 90 day absence as those in the control arm. The evidence on the effect of support groups on retention in HIV care or ART adherence in the context of women initiating HIV care in ANC could also be considered fair at best. Studies have been mixed,[9] [12] [13] combined support groups with other interventions,[13] and still others predate Option B+.[14] [15] To our knowledge, there have not been studies to date on the effect of family support groups on retention of women initiating HIV care through Option B+.

Family Support Groups: The Ministry of Health developed the first edition of Family Support Group (FSG) guidelines in 2004 to address the poor uptake of PMTCT services at the time, and the lack of ongoing psychosocial support for PMTCT clients. According to MOH guidance, the main purpose of the FSGs was to strengthen the provision of PMTCT services to HIV positive mothers, their families and children as primary beneficiaries, by providing an opportunity to meet and support each other psychologically and socially, and to link them with HIV/AIDS prevention, care and treatment services, including early infant diagnosis (EID) interventions.

The specific objectives of the Family Support Group (FSG group) are for members to help each other to:[16]

i. Disclose to each other, friends, relatives, partners and children in order to build a personal support system.
ii. Accept and understand their HIV sero-status and learn how to live positively.
iii. Make informed decisions about safe motherhood
iv. Encourage partners and other family members to get tested for HIV.
v. Learn how and when to access septrin prophylaxis and antiretroviral therapy (ART).
vi. Prepare for adherence to ARVs.
vii. Link and access HIV prevention care, treatment and support services including community social services.

National guidelines state that women are encouraged to attend *facility-based FSGs*, which meet monthly, and if there are challenges in distance, *community-based FSGs* can be formed, which are supposed meet every two months. Sub-groups are formed when FSGs approach 40 members.

Participants: Women and couples testing HIV positive at ANC clinics are referred to FSGs (opt-out) and continue as part of the group until their child is 18 months old. FSG participants also include healthcare workers, caretakers of babies born to HIV positive mothers, and family or friends who can be treatment supporters. FSGs are managed by a facility health worker, who also leads most discussion topics. Participants also elect a leadership committee, including a chairperson. FSGs are also supported by peer educators, who are HIV-positive FSG members that are selected to receive training to provide health education, counseling, and referrals to their peers, as well as community outreach.

FSG meeting content: Meetings are structured to focus discussion on one of 24 health education topics, and external resource persons may be invited. Health facility based FSGs may also provide follow on services are provided after meetings, including ARVs for mothers and children, treatment of opportunistic infections, and booking for CD4/PCR testing.

In short, Family Support Groups exhibit a number of characteristics that by design are factors associated with retention in care or ART adherence,[5] [18] [19] including psychosocial support, assistance with disclosure of status, disclosure to someone other than spouse, peer support, and expert peer support. In addition, FSGs also provide health education and ARV provision, which presumably are also associated with retention.

FSGs were rolled out to nearly all EGPAF-supported sites between 2009 and 2012. In 2011, the MOH reported an FSG coverage of 77%.

2.0 STUDY OBJECTIVES

2.1 Overall objective

The overall objective of this study was to assess the effect of Family Support Groups (FSGs) on retention in care among HIV positive women initiating ART through Prevention to Mother to Child Transmission (PMTCT) services that provide lifelong ART to all pregnant and breastfeeding women ("Option B+"). In addition, the study will sought to determine the clinical and demographic characteristics associated with women who were retained in care and those that were more likely to participate in FSGs, in order to develop recommendations for targeting future retention efforts.

Specific Objectives

1. To evaluate the effect of participation in FSGs on retention in care among women initiating ART through PMTCT Option B+
2. To assess the association of selected demographic and clinical factors with retention in care among women on Prevention to Mother to Child Transmission, Option B+
3. To identify demographic and clinical factors associated with FSG participation

2.3 Research questions

2.3.1 Primary research questions

The primary research questions are:

1. What is the relationship between participation in Family Support Groups (FSGs) and retention among women initiating ART through PMTCT Option B+?
    a. What are the retention rates among women initiating ART through PMTCT Option B+ at 6 months, 12 months, and 18 months after ART initiation?
        i. At each of these three time-in-care points, what is the rate of retention in care among women who participate in Family Support Groups (FSGs) compared with women who do not participate in FSGs?
        ii. At each of these three time-in-care points, what is the proportion of women still on ART among women who participate in Family Support Groups (FSGs) compared with women who do not participate in FSGs?

    b. Among women initiating ART through PMTCT Option B+, what is the magnitude of the association between participation in Family Support Groups (FSGs) and retention in care at 6 months, 12 months, and 18 months after ART initiation?
        i. Is there a dose response relationship in the association between FSG participation and ART retention?
        ii. What is the pattern of FSG participation among women who are or are not retained in care?

2.3.2 Secondary research questions

The secondary research questions are:

    a. What demographic and clinical factors (ie CD4 count, WHO staging, opportunistic infections, hospitalization) are associated with retention in care versus loss to follow-up among women initiating ART through PMTCT Option B+ during the first 18 months of ART treatment?

    b. What are the demographic and clinical factors associated with women who are or are not retained in care?

c. What demographic and clinical factors are associated with FSG participation?

3.0 METHODS

3.1 Study design

This was a retrospective cohort that involved a population of women who had initiated lifelong ART through the PMTCT Option B+ program at 16 selected sites in SW Uganda. These women aged 15 to 49 years were identified primarily from ART registers by checking whether they had been newly enrolled on ART during pregnancy (ANC), or post-partum at the MCH clinic.[3] Triangulation was done using the HIV Care/ART Cards to ensure complete capture of all eligible participants. This study excluded HIV positive women who had been transferred in and out of the study facilities.

Data were abstracted from individual-level HIV care/ART cards in the existing health facility from the time of enrollment into the PMTCT program through 18-month post maternal ART initiation and were entered into a study database. Retention in care and treatment at 6, 12 and 18 months after the date of initiation of ART was assessed, comparing retention between women participating in family support groups (FSGs) and those that opted out of FSG participation. Clinical and demographic factors associated with FSG participation were assessed using data existing medical record data.

3.2 Study population

The study population consisted of all women who initiated lifelong ART through the PMTCT Option B+ program between March and July 2013 at the 16 selected sites. Women were identified from ART registers to ensure complete capture of all eligible participants and screened according to the criteria presented in Table 1.

Table 1: Inclusion/exclusion criteria of participants

Medical record review	
Inclusion criteria	Exclusion criteria
• Woman that initiated lifelong ART through PMTCT program (ie. at ANC, labour and delivery, or during the breastfeeding period) between March 1st and July 31st 2013 inclusive at study health facilities	• HIV positive pregnant/lactating women who initiated ART for treatment at facilities not participating in this study
• Women who were tested HIV positive before current pregnancy/child but who only initiated ART during study period through PMTCT program (ie. at ANC, labour and delivery, or during the breastfeeding period)	• Women in the PMTCT program who initiated ART before March 2013 or after July 2013
	• HIV positive women who declined to initiate in ART
	• HIV- women
	• Women who transferred in from other health facilities
	• Women without HIV care/ART card

[3] At the time of this study, pregnant and women with children under 18 months enrolled in and received HIV/AIDS treatment and care at the MCH clinic until their child turned 18 months old, when they were transferred to the adult ART clinic.

3.2.1 Study Sites

This study was conducted in 16 facilities in the South Western Uganda that were supported by the EGPAF RHITES-SW program. We first identified all EGPAF-supported health facilities that provided Option B+ services during the study period and that had implemented Family Support Groups for at least four years. The 20 sites with highest volume of HIV+ pregnant women initiating HAART through Option B+ in 2014 were identified for the study. However, during study implementation, the actual number of eligible women significantly exceeded the estimates, and further data collection was suspended and the ethics committee was informed about this change. The list of the study facilities that were included in this study are listed in Table 2.

Table 2: Study sites

	District	Health facility		District	Health Facility
1	Bushenyi District	Kyabugimbi H C IV	10	Ntungamo District	Kitwe H C IV
2	Ibanda District	Ibanda Hospital	11	Ntungamo District	Rubaare H C IV
3	Ibanda District	Ishongororo H C IV	12	Ntungamo District	Rwashamaire H C IV
4	Ibanda District	Ruhoko H C IV	13	Rukungiri District	Bugangari H C IV
5	Kanungu District	Kambuga Hospital	14	Rukungiri District	Kebisoni H C IV
6	Kanungu District	Kanungu H C IV	15	Sheema District	Kabwohe H C IV
7	Kanungu District	Kihihi H C IV	16	Sheema District	Kitagata Hospital
8	Mitooma District	Mitooma H C IV			
9	Ntungamo District	Itojo Hospital			

3.3 Sample size and rationale

All women in the PMTCT program who had received antenatal, labor and delivery or postnatal care at study facilities that met the inclusion criteria were enrolled in the study.

Program data from 2014 indicated that an approximately 420 HIV-positive pregnant women initiated HIV care each quarter across the 16 sites, of which an estimated 37% participated in FSGs. Extrapolating, we estimated approximately 560 study participants for which data could be collected within the study timeframe. Table 3 presents the minimal detectable effect size the study was powered to under different assumptions of retention rates among women not participating in FSGs, and design effect assumptions of 1.5 and 2.0.

As indicated, significantly more women met the study inclusion criteria, and the final study sample size consisted of 1,020 women from 16 health facilities.

Table 3: Minimal detectable difference in increased retention rate

Estimated retention rate among unexposed (ART patients[4] not participating in FSGs)	Intercluster correlation coefficient	Detectable difference
30%	.03[5]	14%
	.06[6]	17%
35%	.03	14%
	.06	18%
40%	.03	15%
	.06	18%
45%	.03	15%
	.06	18%
50%	.03	14%
	.06	17%
55%	.03	14%
	.06	17%

3.4 Study Outcomes

The primary outcome measure was the comparison of women participating in FSGs and those that did not join FSG's.

- Proportion of women initiated on ART who are retained in HIV care during the first 18 months of treatment

Secondary outcome measures (comparison of women participating in FSGs vs non-participants)

- Proportion of women initiated on ART who remain on ART during the first 18 months of treatment
- Proportion of women during the first 18 months of treatment who were at WHO Stage III or IV at first and last clinical visit at 18 months.
- Proportion of women during the first 18 months of treatment with CD4 count <200 at first and last clinical visit at 18 months
- Proportion of women during the first 18 months of treatment with TB or other opportunistic infection documented
- Proportion of women with documented hospitalizations during the first 18 months of treatment

3.5 Study Procedures

Data Collection

Data collection was conducted by research assistants who were selected from among clinic data clerks that entered ART patient medical records into the national electronic database at assigned health centers and hospitals. As such, they had already been trained on how to extract patient-level data from HIV care/ART cards, ART registers and

[4]Since there were no estimates available for pregnant women, we collected data on a convenience sample of 74 ART patients at six sites in 2014. The 12-month retention rate among the 40 patients that did not participate in a FSG was 40% and the 6-month retention rate was 60%.

[5] Corresponds to a design effect of 1.5

[6] Corresponds to a design effect of 2.0.

other sources of PMTCT program data at the facility. Research assistants were selected based on their previous performance relative to other data clerks on criteria such as reliability, accuracy, and demonstrated knowledge.

Research assistants' training was carried out over a period of five days. They were trained on the protocol and the standard operating procedures, screening, enrollment log and all other study tools. Piloting of data collection was carried out from non-participating study facilities of Mbarara Municipal Council, Kinoni HC IV and Ndeija HC III in Mbarara district. Research Assistants were supervised during data collection to ensure that study procedures were correctly followed.

All HIV positive pregnant and postpartum women in the PMTCT program who initiated ART during the study time period were assigned a unique study identification number that was used on all data collection instruments and the study electronic database. An enrollment log containing the name of the study participants, ANC, ART and other clinic numbers were maintained in order to link information across service delivery areas and registers (ie ANC and PNC, ANC and HIV clinic etc) since there was no single unique identifier that was consistently recorded across these service delivery registers. This log was maintained securely with access limited to only the study personnel. After all data had been captured and cleaned, this log was destroyed.

During data collection, the HIV Care/ART Card was the primary source of study data, supplemented and verified by other sources such as antenatal register, maternity register, ART registers and FSG registers. HIV Care/ART card were issued to all women who had initiated on ART and they were kept within MCH clinic for at least 18 months until the mother could be transferred to HIV care clinics. Data was entered directly into Microsoft Access database. The database had inbuilt data quality checks. Data was continuously entered and systematically backed up. The study database was maintained in the EGPAF Uganda offices in Mbarara with copies sent to EGPAF Washington DC for analysis.

Data Analysis

Data analysis was performed using STATA version 14.2. Categorical baseline characteristic variables were summarized using frequencies and percentages of participants for those participating and not participating in the FSG. Retention in care at 6 and 12 months was defined as having had a documented clinic visit in the six-month period three months before and three months after the end of the corresponding time period. For instance, a woman was considered retained in care at 12 months if she had had at least one clinic visit between nine and 15 months after initiating ART. Because clinic visit data beyond 18 months were not consistently available, retention in care at 18 months was defined as having had a clinic visit during the 90 days before the end of the 18-month period after ART initiation (ie between 15 and 18 months post ART initiation). Women with documented deaths or transfers out of study facilities were excluded from retention estimates.

Retention in care *survival* was estimated for both study arms and compared using a log-rank test to determine whether there was a difference in retention in care survival distributions between the sample of those participating in the FSG program and those not participating in the FSG. Type I error rate (α) for statistical tests was set at 0.05. Attrition was defined as having experienced an attrition event, ie. death or lost to follow up (LTFU).

Cox proportional hazard models were used to test the independent association of FSG participation, women's age at the time of initiating PMTCT care, having HIV family members, marital status, and pregnancy status at the time of ART initiation with retention in care survival among the women. Effect modification was assessed by including interaction terms between the FSG participation group variable and the other independent variables in the model. The relationship between the number of FSG visits attended and retention in care survival was assessed using Kaplan Meier curves among those who participated in the FSGs.

Data quality assurance and quality control

To ensure data quality control, piloting was conducted in 3 non participating health facilities during research assistants training. This was critical in ensuring that tools such as screening, enrollment were in tandem with data procedures and processes at the sites. At least 5% of the data extracted was verified using manual double-key data entry at each health facility by a data quality supervisor, and additional verification was conducted according to the level of accuracy demonstrated by data entry clerk. The data was transferred into STATA 14.2 for analysis.

The study coordinator and the co-investigator also conducted periodic checks on data validity of key variables. Where data deficiencies were identified, they were corrected and fed back to appropriate research assistant for appropriate action.

3.6 Ethical considerations

This protocol was reviewed and approved by the Mbarara University Science and Technology Institutional Review Committee/Board, as well as the Chesapeake Institutional Review Board in the US. It was then registered with the president's office under the Uganda National council of science and Technology (UNCST).

Data collectors recorded patient identifiers such as the name and ART number to allow for linkages across registers, and assigned them to a unique study ID on a study enrollment log. Data collection instruments included only the study ID. The log with the name and the ART number-study ID link was stored in a locked cabinet with access limited to research staff when not in use. Once the data had been abstracted and verified, and the data are analyzed, this log was destroyed. The IRB granted a waiver of consent from the women whose records were reviewed to assess client retention in care, as the study presented no more than minimal risk to participants and seeking for consent was not practicable.

All research staff members completed a training in human subjects' protection with FHI360 prior to starting the study data collection. All research assistants were made to sign a confidentiality agreement prior to data collection.

4.0 RESULTS

4.1 Introduction

Figure 1 presents the flow of study screening and enrollment. Between March and July 2013, 2,269 mothers initiated lifelong ART through the PMTCT program in 16 study facilities in South-western Uganda. All were screened for eligibility and 1020 mothers were eligible to participle in the study and enrolled. After exclusion of 8 participants due to discrepancies in the HIV card data that could not be resolved, 455 mothers participating in the standard of care and 557 participating in the FSG intervention remained for analysis.

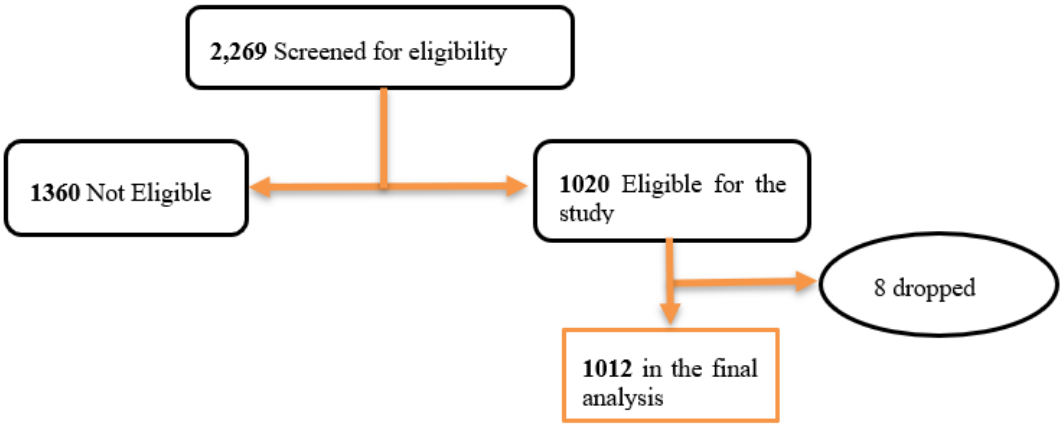


Figure 1. Participant screening and enrollment.

4.2 Description of Characteristics of mothers in the study

Table 4 summarizes the characteristics of mothers who participated in FSG and those who did not participate in the FSG. More than half the mothers (55.0%) who initiated ART through the PMTCT program opted to join a family support group. Study participants were a mean age of 26 years (IQR = 22-29), most were married (84.2%), and one out of five had an HIV-positive family member. The vast majority of women (95.9%) were on the national first line recommended ARV regimen, TDF-3TC-EFV. Although most study participants did not have a homebased care provider (83.5%) or belong to an ARV support group (90.7%), a large proportion (83.1%) had a treatment supporter.

Overall, study participants in the two study arms were similar. A significantly greater proportion of FSG participants had a home-based care provider 19.7% compared to. 12.5% of non FSG participants. In addition, the two groups were significantly different with respect to initial CD4 count, with a smaller proportion of FSG participants initiating care with a CD4 count <200 cells/μ 4.9% while 13.9% of participants initiated with care CD4 count <200 cells/μ.However, as might have been expected, a high proportion of women did not have a documented initial CD4 count in their medical records (42.8%).

Table 4. Baseline Characteristics of HIV-Infected Women Initiating ART through PMTCT by Cohort Arms

Characteristics	Study Arms Standard of Care	Family Support Group	Total	P*
Total women enrolled	455	557	1012	
	No. (%)	No. (%)	No. (%)	
Age				0.157
15-19	54 (12.1)	45 (8.1)	99 (9.9)	
20-24	168 (37.5)	204 (36.8)	372 (37.1)	
25-29	126 (28.1)	164 (29.5)	290 (28.9)	
30+	100 (22.3)	142 (25.6)	242 (24.1)	
Missing	7	2	9	
Marital Status				0.393
Not Married	75 (17.5)	74 (14.3)	149 (15.7)	
Married	353 (82.5)	443 (85.7)	796 (84.2)	
Missing	27	40	67	
Treatment Supporter				0.851
No	78 (17.1)	93 (16.7)	171 (16.9)	
Yes	377 (82.9)	464 (83.3)	841 (83.1)	
Missing	0	0	0	
Home Base Care Provider				0.002
No	398 (87.5)	447 (80.3)	845 (83.5)	
Yes	57 (12.5)	110 (19.7)	167 (16.5)	
Missing	0	0	0	
HIV-Positive Family Member				0.470
No	278 (78.1)	318 (75.9)	596 (76.9)	
Yes	78 (21.9)	101 (24.1)	179 (23.1)	
Missing	99	138	237	
Initial ART Regimen				0.035
TDF-3TC-EFV	429 (94.5)	540 (97.1)	969 (95.9)	
Other regimen	25 (5.5)	16 (2.9)	41 (4.0)	
Missing	1	1	2	
Initial CD4 Count (cells/μL)				0.007
0-199	26 (13.9)	12 (4.9)	38 (8.8)	
200-349	22 (11.8)	41 (16.7)	63 (14.5)	
350-499	36 (19.3)	46 (18.7)	82 (18.9)	
500-1600	103 (55.1)	147 (59.8)	250 (57.7)	
Missing	268	311	579	
Currently pregnant				0.454
No	185 (40.7)	240 (43.1)	425 (42.0)	
Yes	269 (59.3)	317 (56.9)	586 (58.0)	
Missing	1	0	1	
ARV Support Group				0.353
No	417 (91.6)	501 (89.9)	918 (90.7)	
Yes	38 (8.4)	56 (10.1)	94 (9.3)	
Missing	0	0	0	

P*: p-value from a chi-2 test of independence

4.3 Relationship Participation in Family Support Group and Retention in HIV care under Option B+

Table 5 summarizes the study mothers' retention in care. As might have been expected, retention in HIV care and antiretroviral treatment decreased over time. Retention of women initiating HIV care under Option B+ was higher at 6 months follow up (84.2%) compared to retention in HIV care at 18 months (67.8%). There were variations in retention of women who participated in the FSGs and those who didn't participate in the FSG at 6 months and 18 months of follow up period, with women enrolled in FSG having a higher retention study arm compared to those who did not enroll in the FSG: 6 months follow up retention: 91.7% for women who enrolled in FSG compared to 75.1% for women who did not enroll in the FSG, and at 18 months follow up retention: 75.7% for women who enrolled in FSG and 58.1% for women who did not enroll in the FSG.

Table 5. Retention in care of HIV-Infected Women Initiating ART through PMTCT by Study Arms

	Study Arms		
Outcome	Standard of Care	Family Support Group	P-value
Total women enrolled	449	544	
	No. (%)	No. (%)	
Retention*			
Retention at 18 months	261 (58.1)	412 (75.7)	0.000
Retention at 12 months	296 (65.9)	467 (85.9)	0.000
Retention at 6 months	337 (75.1)	499 (91.7)	0.000

*****Retention at X months was defined as being alive and in care 90 days before X months, excluding transfers.

P*: p-value from a chi-2 test of independence

Figure 2 shows a significant difference between the two study arms in terms of the probability of not being retained compared to women who received just standard of care (log-rank test, $p < 0.000$). In fact, the Kaplan Meier plots illustrate how the gap in retention is apparent nearly immediately after ART initiation. There is approximately a 10-percentage point gap between study groups immediately after ART initiation, highlighting women who initiated care and never returned for continued care. This gaps widens to slightly more than 15-percentage points at 18 months.

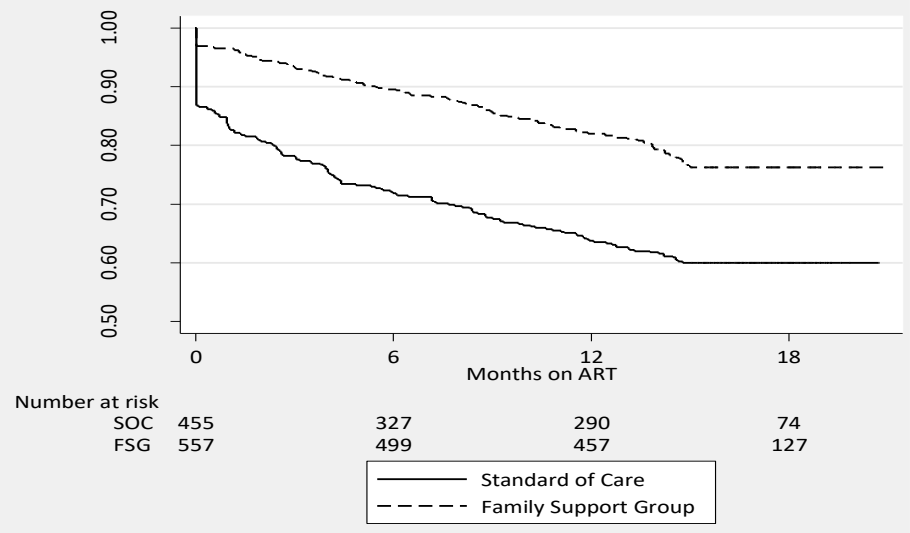


Figure 2. Kaplan-Meier of retention in care probability estimates under Option B+ by study arm

Table 6 presents the final Cox proportional hazard model estimates of the effect of the family support group on lost to follow-up, with adjustment for covariates. Women who participated in FSGs had a 43% reduced hazard of attrition compared to women who did not participate in the FSG, when adjusted for remaining covariates HR=0.57 (95% CI: 0.36-0.75). The FSG and pregnancy interaction term was significant at $p<0.02$, suggesting that the FSG intervention is more effective in improving retention in care among those who initiated ART while pregnant compared to those who initiated ART while lactating

Table 6 also provides additional insight into other factors associated with retention. First, women with an HIV-positive family member had a 40% reduced hazard of attrition HR=0.60 (95% CI: 0.42-0.86), when other covariates were held constant. In addition, with respect to age, the hazard of attrition decreased with each increasing age group (hazard estimates were significant). Women aged 30+ years had a 70% reduced hazard of attrition compared to women aged 15-19 years, when adjusted for remaining covariates HR=0.30 (95% CI:0.19-0.47). Figure 3 shows the Kaplan Meier estimates for retention in care over time for the four age groups. Finally, though the univariate analysis indicated that women who initiated ART during pregnancy were at increased hazard of not being retained in care, compared to women initiating during the breastfeeding period, the adjusted model indicated no difference between the two groups.

Table 6. Hazard ratio estimates from the Cox proportional hazards model and associated 95% confidence intervals.

Variable	Hazard Ratio	95% CI	P
Study Group			
Standard of Care	1.00		
Family Support	0.57	(0.36, 0.75)	0.000
Age (years)			
15-19	1.00		
20-24	0.52	(0.36, 0.75)	0.000
25-29	0.46	(0.31, 0.68)	0.000
30+	0.30	(0.19, 0.47)	0.000
HIV positive Family Member			
No	1.00		
Yes	0.60	(0.42, 0.86)	0.006
Marital Status			
Married	1.00		
Divorced/separated	0.97	(0.57, 1.65)	0.923
Single/never married	0.88	(0.54, 1.43)	0.603
Widowed	1.40	(0.56, 3.46)	0.470
Pregnant at ART Initiation			
No	1.00		
Yes	1.05	(0.80, 1.37)	0.743

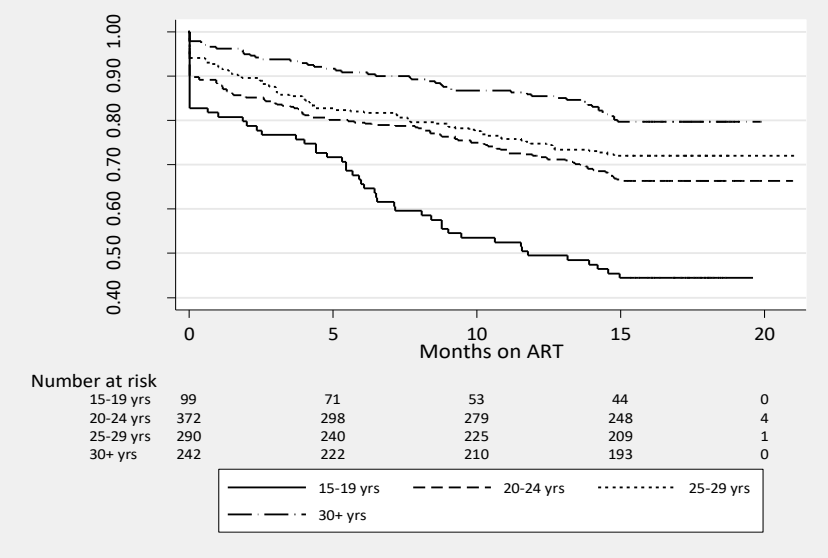
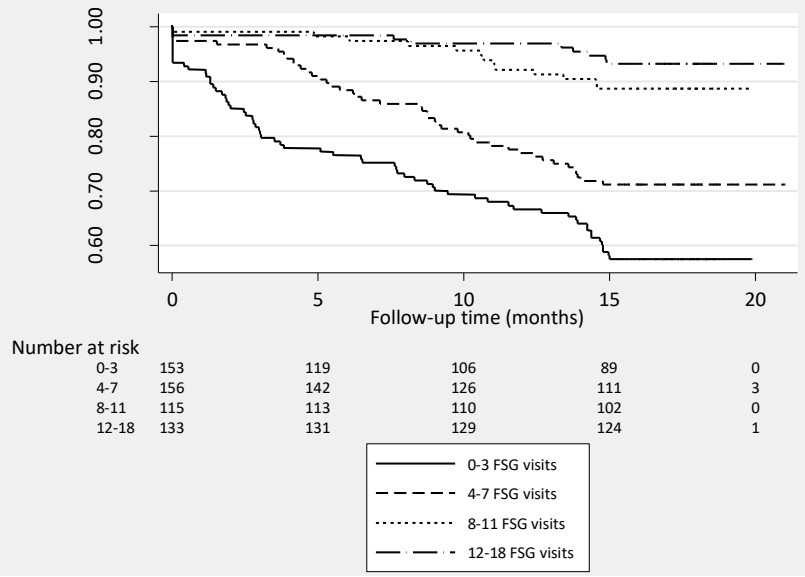


Figure 3. Kaplan-Meier of retention in care probability estimates, grouped by age group.[7]

Figure 4 below shows the retention patterns of women when grouped by FSG attendance levels as indicated in the figure legend. Women who attended more FSG visits (ie group meetings) had a greater probability of being retained in care over time compared to mothers that had fewer FSG visits. The direction of this dose-effect was consistent for all the study participants.



[7] Figure 3 includes age group 15-19 years which has much smaller numbers than the other age groups, contributing to the drastic proportion drop.

Figure 4. Kaplan-Meier of retention in care probability estimates amongst the participants in the FSG group, grouped by number of visits attended.

5.0 DISCUSSION OF STUDY FINDINGS

This study evaluated the effect of FSGs on retention in HIV care as the PMTCT Option B+ approach was implemented in Uganda. It provides unique findings on the relationship between participation in family support groups and retention in care in Uganda. Overall, women who initiated ART under Option B+ and attended FSGs had a higher retention in HIV care at 6, 12, and 18 months after ART initiation compared to women that did not participate in FSGs. Similarly, adjusted analysis using the Cox proportional hazards model, showed that women in the FSG group were significantly less likely to experience hazard of attrition.

Retention at 12 months post ART initiation was at 85.9% for FSG participants, compared to 65.9% for women who did not participate in the FSG. For reference, EGPAF-supported sites reported a 12-month retention rate for all adults of 81% in 2013. Previous studies[5] have observed lower retention rates at larger, urban, public hospitals compared to smaller, rural, private facilities. Since sites for the current study were selected among the high volume health facilities, the lower retention observed among women who did not participate in the FSG compared to all adults is generally consistent with findings from previous studies.

There are a few findings that may have implications for practice. First, the finding that FSGs are more effective in improving retention in care among women initiating ART during pregnancy compared to those initiating ART during the breastfeeding period reinforces the need for additional support to be provided to women enrolling in care during pregnancy to ensure they are retained in care. Initiation of ART during pregnancy compared to initiation of ART during breastfeeding is a known risk factor for poor retention in HIV care in the context of Option B+.[5] A 2016 Malawi study[17] noted that women who initiated ART during the breastfeeding period were more likely to be older and have more advanced disease, suggesting that such women may be more likely to enroll in care when they are experiencing symptoms. This finding suggests that health workers may consider screening women that are initiating ART and encouraging pregnant women to join FSGs to help ensure that their needs are met. For the same reason, health workers might also consider pregnancy status as a rationale for dividing women into subgroups; current guidelines already recommend dividing the FSG into subgroups as memberships grow.

The odds of being retained in PMTCT program were 3 times higher for mothers aged 30 years and above compared to other age groups. The younger age groups were comparatively poorly retained. EGPAF program data also show a similar trend of younger mothers poorly retained on ART. Although the reasons are not so clear some studies have shown a significant association between age and stigma, showing higher levels of stigma in the younger age groups which reduces with addition in age. These could possibly explain the poor attendance in family support groups bearing in mind that these groups are not differentiated and structured to cater for age related needs in a single group. There have been challenges in handling the adolescents and younger people living with HIV on ART. Interests vary by age, and the younger mothers may find these meetings less appealing. This is a very important finding basing on the recent findings from Uganda population HIV impact assessment (UPHIA) that show a high HIV prevalence amongst adolescents and young women in Uganda. There is need to structure and implement differentiated FSGs to make them suitable and more appealing for the younger mothers.

The dose effect relationship between FSG attendance and retention in care (Figure 4), suggests that health workers should encourage FSG participation throughout the lifespan of the pregnancy/breastfeeding period, not just at ART initiation, prioritizing women at higher risk of attrition. Efforts are needed by program implementation to ensure that mothers join family support groups and consequently attend all the scheduled visits needed to receive peer and psychosocial support and attain all the benefits which occur.

The overall finding that women initiating Option B+ who participated in FSGs experienced higher retention rates than those who did not participate in FSG differs from findings from the 2014-16 EPAZ trial in Zimbabwe,[9] which studied the effect of Mother Support Groups (MSGs) on 12-month postpartum retention rates of HIV-exposed infants. The EPAZ trial was not able to demonstrate a difference in retention between whose mothers who participated in MSGs, compared to those whose mothers received standard of care. Unlike the FSG study, the

EPAZ study was a prospective trial that assigned women at randomized sites to participate in MSGs, and the study reported a substantial proportion (27%) that did not consent to enroll in the study. Women frequently reported requiring their partner's approval before providing written consent, and most (85%) enrolled mothers had disclosed their HIV status to their partner at enrollment. Study authors hypothesized that women who enrolled in the study were more likely to have disclosed their status and thus were more likely to be retained.[8]

Another difference between the two studies, is the fact that FSGs facilitate ARV dispensation after FSG meetings, reducing the level of effort needed to maintain routine care. A 2012 South African study[7] focused on adherence "clubs," in which stable patients were shifted from nurse-led individual consultations to counselors-led group consultations. In addition to leading group health discussions, counselors dispensed ARVs, after administering a symptom-based general health assessment. Study authors indicated that most patients that were given the option of transitioning to an ARV club-based care did so *due to the prospect of much less time spent waiting for medicines*. The study found that club participation reduced loss-to-care by 57%. While the adherence club model was created to increase efficiency in care, it was unclear the extent to which the model provided peer psychosocial support.

This suggests that an improved Family Support Group model could include the following:

- Greater efficiency of a differentiated care model for treatment (ie reduced overall waiting time, including to collect ARVs, than through standard of care)
- Peer and psychological support targeting specific needs of women at risk for attrition, possibly achieved by subgrouping based on specific risk groups, including young women, women who are newly initiated on ART, women who initiated during pregnancy, women who have not disclosed their status (family, partner)

5.1 LIMITATIONS

The study carries inherent limitations. First the study was retrospective and relied on medical record abstraction. Estimates of retention could have been subsequently limited by the quality of the data and the capacity of the health care system to document outcomes such as transfers and deaths. More specifically, Cox proportional hazards estimates carry the assumptions of independence of censoring and survival (ie retention), which are reliant on quality of documentation.

In addition, reliance on observational data subjected the study to selection bias, because women who chose to participate in FSGs were more likely to have disclosed their HIV status or have felt more comfortable disclosing their status, and thus they were also more likely to be retained for that reason. Since we were not able to correct estimates for this omitted variable, the selection bias would have over-estimated the effect of FSGs.

[8] The MSGs featured biweekly meetings from ANC to six-month postpartum facilitated by trained HIV-positive mothers, and health care workers using a standard curriculum of PMTCT discussion topics promoting experiential learning and peer psychosocial support. Differences between MSGs in Zimbabwe and FSGs in Uganda include meeting frequency, target participant (ie women vs women and their families), and the fact that the FSG structure includes ARV provision to mothers and children. Study design differences include directionality (prospective vs retrospective) and study eligibility (all HIV-positive women vs newly initiated on ART).

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