

Impact of Facility-Based Mother Support Groups on Retention in Care and PMTCT Outcomes in Rural Zimbabwe: The EPAZ Cluster-Randomized Controlled Trial

Geoff Foster, MBBS, MRCP (Paeds),*† Joanna Orne-Gliemann, MPH, PhD,‡§ Hélène Font, PhD,‡§
Abigail Kangwende, MBBS, MPH,|| Vhumani Magezi, PhD,¶ Tonderai Sengai, MSc,†
Simba Rusakaniko, PhD,# Bridget Shumba, MPH,† Pemberai Zambezi, MSocSc,† and
Talent Maphosa, MBBS, MDS**

Background: Prevention of mother-to-child transmission elimination goals are hampered by low rates of retention in care. The Eliminating Paediatric AIDS in Zimbabwe project assessed whether mother support groups (MSGs) improve rates of retention in care of HIV-exposed infants and their HIV-positive mothers, and maternal and infant outcomes.

Methods: The study involved 27 rural clinics in eastern Zimbabwe. MSGs were established in 14 randomly selected clinics and met every 2 weeks coordinated by volunteer HIV-positive mothers. MSG coordinators provided health education and reminded mothers of MSG meetings by cell phone. Infant retention in care was defined as “12 months postpartum point attendance” at health care visits of HIV-exposed infants at 12 months of age. We also measured regularity of attendance and other program indicators of HIV-positive mothers and their HIV-exposed infants.

Results: Among 507 HIV-positive pregnant women assessed as eligible, 348 were enrolled and analyzed (69%) with mothers who had disclosed their HIV status being overrepresented. In the intervention arm, 69% of infants were retained in care at 12 months versus 61% in the control arm, with no statistically significant difference. Retention and other program outcomes were systemati-

cally higher in the intervention versus control arm, suggesting trends toward positive health outcomes with exposure to MSGs.

Discussion: We were unable to show that facility-based MSGs improved retention in care at 12 months among HIV-exposed infants. Selective enrollment of mothers more likely to be retained-in-care may have contributed to lack of effect. Methods to increase the impact of MSGs on retention including targeting of high-risk mothers are discussed.

Key Words: HIV, retention, peer support, Zimbabwe, PMTCT

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INTRODUCTION

The Option B-plus strategy adopted by Zimbabwe in 2013 for the prevention of mother-to-child transmission (PMTCT) involves starting pregnant and breastfeeding HIV-positive women on antiretroviral (ARV) treatment (ART) as soon as possible after diagnosis and continued for life. To eliminate pediatric HIV infections and improve both maternal and infant health outcomes, HIV-positive women and their HIV-exposed infants must adhere to ART and be retained in care.

In 2015, it was estimated that 85% of HIV-positive pregnant women in Zimbabwe received ARVs for PMTCT, 75% of infants received ARV prophylaxis in the first 6 weeks of life, and 55% of HIV-exposed infants received early infant diagnosis.¹ In 2014, attendance at the fourth antenatal care (ANC) visit of HIV-positive mothers was estimated at 45%.² ART initiation and retention in care were identified as important bottlenecks to achieve 2015 pediatric HIV elimination targets in Zimbabwe.³ No late postnatal data on national retention rates of HIV-positive mothers or their exposed infants in Zimbabwe are available.

Interventions such as mobile phone technologies and community health workers improve some aspects of PMTCT service delivery,^{4–6} but evidence for improving late postpartum retention is weak. Selection bias, lack of controls, short postpartum follow-up, and high loss to follow-up rates characterize many intervention studies.⁷ Furthermore, many

From the *Ministry of Health and Child Care, Mutare, Zimbabwe; †Family AIDS Caring Trust, Mutare, Zimbabwe; ‡INSERM U1219—Centre Inserm Bordeaux Population Health, Université de Bordeaux, Bordeaux, France; §Université de Bordeaux, ISPED, Centre INSERM U1219—Bordeaux Population Health, Bordeaux, France; ||Clinical Research Centre, Africa University, Mutare, Zimbabwe; ¶North West University, School of Basic Sciences, South Africa; #University of Zimbabwe, College of Health Sciences Harare, Zimbabwe; and **Organization for Public Health Interventions and Development, Harare, Zimbabwe.

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Correspondence to: Geoff Foster, MBBS, MRCP (Paeds), Family AIDS Caring Trust, Box 970, Mutare, Zimbabwe (e-mail: geoffoster53@gmail.com).

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interventions are established in special settings involving high program costs such as salaries and incentives for mothers preventing their scale-up by national health systems.^{6,8}

Peer interventions that involve HIV-positive mothers to conduct mother support groups (MSGs) and mentor other HIV-positive mothers at health facilities or in communities are “promising practices” to strengthen PMTCT programs.⁹ MSGs may improve PMTCT outcomes such as retention in care and ART adherence by addressing women’s information needs, reducing stigma, encouraging disclosure, improving male partner participation, and increasing facility-based deliveries.^{10,11} No randomized trial has previously addressed the impact of MSGs on PMTCT outcomes.

The Eliminating Paediatric AIDS in Zimbabwe (EPAZ) study aimed to evaluate whether MSGs newly established at clinics improved HIV-exposed infants’ and their HIV-positive mothers’ retention rates in postnatal follow-up and other program outcomes.

METHODS

Study Design and Setting

The EPAZ study was a cluster-randomized controlled trial with clinics as cluster units. The full trial protocol is published elsewhere.¹² The trial was implemented in clinics located within rural communal and commercial farming areas in Mutare and Makoni districts of Manicaland province, Zimbabwe.

Study Population

Women were eligible for enrollment if they were HIV-positive, 18 years or older, lived in the clinic catchment area, and were under 35 weeks of gestation. Women in the intervention arm were eligible if they also consented to attend MSGs.

MSG Intervention

MSGs were established at intervention clinics 4–7 months before the start of enrollment. MSGs were planned to function twice per month. HIV-positive pregnant women assessed for trial eligibility at their first ANC booking were invited to attend MSGs by health care workers (HCWs) and to attend meetings regularly until graduating from MSGs after 6 months postpartum.

At each clinic, 2 HIV-positive mothers with recent PMTCT service experience were appointed as coordinators to lead MSGs. They received standardized training on group management, liaison with HCWs and reporting. Each coordinator received a simple phone and a monthly US\$10 card to provide MSG meeting reminders to members, including an additional reminder to mothers who missed a meeting. Coordinators were volunteers and received no financial allowances.

HCWs and MSG coordinators facilitated structured learning activities at each MSG session using a standardized curriculum of 8 PMTCT topics over each 4-month cycle.¹³ Such group discussions and participatory processes promote experiential learning and increase women’s contacts and

relationships with HCWs.¹⁴ HIV-positive women received psychosocial support from other women during meetings; interactions with peers may be more important in influencing health-related behaviors than regular meeting attendance or information acquisition.¹⁵

Study Procedures and Data Collection

HCWs received standardized training in study procedures: they assessed HIV-positive women for eligibility and enrolled eligible women who agreed to provide written consent. Routine data consigned in 11 Ministry of Health and Child Care (MOHCC) facility registers, patient cards, and additional EPAZ study data on enrolled women were collected by HCWs. MSG attendance data were collected by MSG coordinators, assisted by trial staff. Data were abstracted by data collectors during monthly site visits and consigned in participant Case Report Forms in a 3-level data verification process.

Outcomes

The primary outcome is a proxy for retention in care at 12 months, namely “12 months postpartum point attendance” of HIV-exposed infants at 12 months of age at any clinic appointment (not only PMTCT-specific visits but also for illness, immunization, etc.). An infant who visited the clinic at 12 ± 1 month (D331–390) was considered as retained at 12 months of age. We constructed a “12-month regular attendance” indicator as a measure reflecting regularity in attendance. An infant who attended at least once in four 60-day periods during the first year of life was considered a regular attender at 12 months of age (Table 1). According to MOHCC policy, HIV-exposed infants should be seen at 1, 6, and 12 weeks old and monthly thereafter. HIV-positive mothers should be seen monthly throughout their antenatal and postnatal periods with those newly diagnosed also being seen 2 weeks after ART initiation.¹⁶ During the course of this study, many clinics dispensed ARVs for 2 and even 3 monthly intervals.¹⁷

Secondary outcome measures were (1) retention in care of HIV-positive mothers at 12 months postpartum, constructed in the same way as attendance indicators for infants (ie, including PMTCT-related visits, ART visits but also family planning, illness, etc.); (2) other health indicators, namely number of ANC visits, place of delivery, use of family planning methods at 12-month postnatal, disclosure to partner at 12 months postpartum, early infant diagnosis, and completion of vaccination schedule by 12-month rates (Table 1).

Statistical Power

The trial was 80% powered to detect a 50% increase in the 12-month attendance rate among infants, with an estimated baseline rate of 50% in the control arm versus 75% in the intervention arm.¹² The initial calculations assumed a 2-sided significance level of 5%, an intracluster correlation coefficient (ICC) of 0.15, 15 clusters by arm, and made allowance for 20% of nonavailable data. The sample size calculations were revised in 2015, using an ICC of 0.1

TABLE 1. Variables' Description

	Outcome	Definition
Primary outcome		
Infant retention	Point attendance of HIV-exposed infants at 12-mo postnatal follow-up	At least 1 visit at the clinic between 331 and 390 d postdelivery
Secondary outcomes		
Infant retention	Regular attendance of HIV-exposed infants over the 12-mo postnatal follow-up	At least 1 visit at the clinic in 4 or more of 6 consecutive 60-d periods between 1 and 360 d postdelivery
Mother retention	Point attendance of HIV-infected mothers at 12-mo postnatal follow-up	At least 1 visit at the clinic between 331 and 390 d postdelivery
	Regular attendance of HIV-infected mothers over the 12-mo postnatal follow-up	At least 1 visit at the clinic in 4 or more of 6 consecutive 60-d periods between 1 and 360 d postdelivery
Other maternal and child health indicators	Full dose of ANC visits	At least 4 recorded ANC visits
	Delivery place	Delivery within a health facility
	Use of family planning methods at 1-yr postnatal	At least 1 family planning visit between 6 and 12 mo
	Rapid HIV testing of infants	Early infant diagnosis performed at 6 wk (± 2 wk)
	Infant's DTP (pediatric diphtheria, tetanus, and acellular pertussis)/measles vaccination	Immunization schedule up to date by 12 mo

EPAZ trial (2014–2016).

As we used an intention-to-treat approach for all variables, each outcome was coded as YES/NO, but the NO included several outcomes. For children, the value "NO" included Absence of the variable, Death, Moved or transferred out and unknown status. For mothers, the value "NO" included Absence of the variable, Death, Stillbirth/Abortion/Miscarriage, Moved or transferred out and unknown status.

after expert review by the INSPIRE Scientific Advisory Group based on estimates from a comparable study.¹⁸ The minimum number of HIV-positive pregnant women to be enrolled in each arm was 105. Each cluster was expected to recruit at least 7 HIV-positive pregnant women.

Randomization

In the original 3-arm EPAZ trial design, the study zone was divided in 2 districts into 15 groupings, each composed of 2–6 clinics grouped according to geographical proximity (63 clinics in total). The 15 groupings with the largest numbers of HIV-positive women seen in ANC in 2012 were selected. The groupings were ranked by size and assigned to 5 triplets of similar size with both districts represented in each triplet. Finally, the 3 groupings of each triplet were randomly assigned to the 3 proposed trial arms [standard of care, point-of-care (POC) infant HIV testing, and POC plus MSGs]. The process was repeated until each arm contained at least 2 groupings from each district. When the POC intervention became unavailable, arm 2 of the trial was dropped, the initial randomization of groupings was preserved. Within the 10 randomized groupings, 30 clinics were selected (15 by arm) according to size, staff, and accessibility. After randomization, 3 clinics among the 30 were removed because of difficulties in implementation (Fig. 1). The randomization procedure was performed manually by an MOHCC epidemiologist.

Statistical Analysis

An intention-to-treat approach was adopted for all analyses. Descriptive statistics are presented with frequencies and percentages. Continuous variables were categorized using quantiles as nonnormally distributed. Four pairs of twins were born during the trial. To avoid nonindependence between

respective twins' data, we randomly dropped one of each pair. A generalized linear mixed-effects model with a logit link function was used to test the impact of the intervention on infant retention in care at 12 months postpartum. To take into account the randomization process, groupings and clinics were included as nested random effects and clinic size was included as a fixed effect. A fixed effect estimated randomization to the intervention arm. Multivariate analyses were performed to test if the impact was confirmed after adjustment on key covariates known to be potentially associated with retention in care (Table 1). A similar procedure was used to estimate the effect of the intervention on secondary outcomes. Analyses were performed on imputed and nonimputed data sets to check for consistency. R-software (version 3.0.2) was used for data analyses.

Ethics

The Medical Research Council of Zimbabwe and the WHO Ethical Review Committee provided ethical approval for this study in 2012. The trial is registered as NCT02216734 with the U.S. National Institutes of Health.

RESULTS

In the 27 randomized clinics, among 977 pregnant HIV-positive women booking for ANC between July 2014 and October 2015, 798 (82%) were assessed for trial eligibility by HCWs (Fig. 1). Baseline characteristics of assessed women were similar to nonassessed women apart from gestational age and distance from the clinic; 48% of the nonassessed booked after 21 weeks of gestation compared with 37% of the assessed. Forty-five percent of the nonassessed were living further than 7 km from the clinics compared with 32% of the assessed (Table 2).

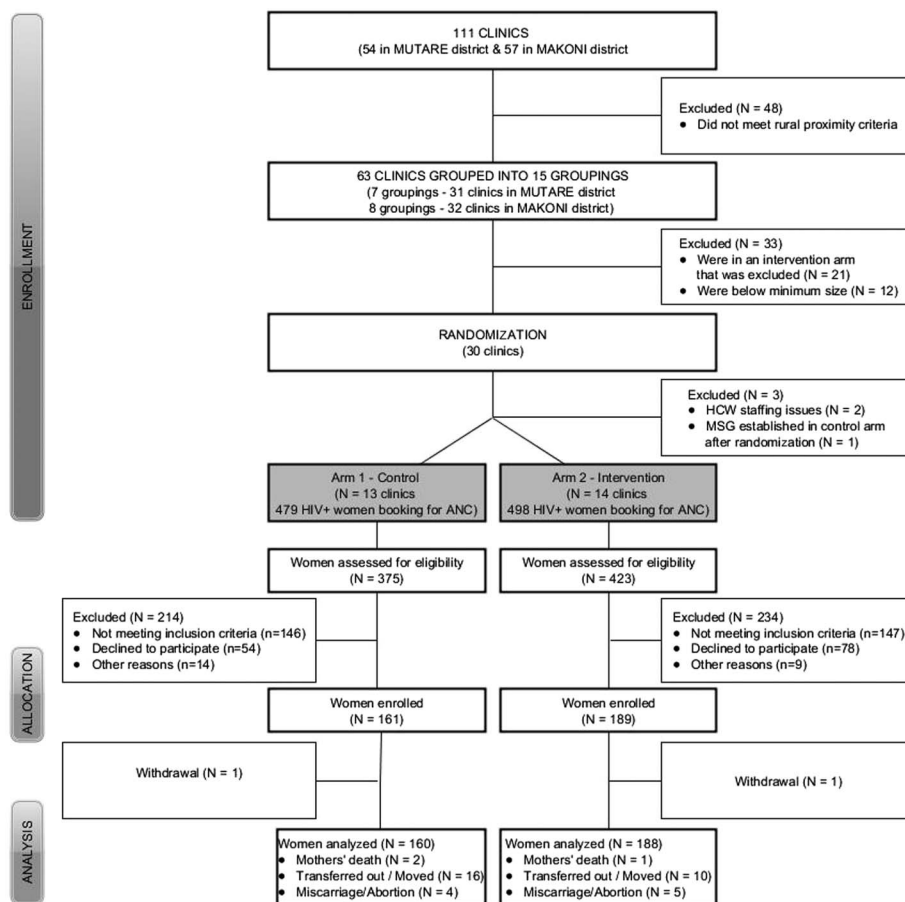


FIGURE 1. Flow diagram of the study. EPAZ trial (2014–2016).

Among the 507 women assessed as eligible, 348 were enrolled (69%) and 2 women withdrew during the study. Enrolled women were more likely than those assessed as eligible but nonenrolled to have a higher parity, to be married, and to be on ART at first booking (Table 2).

In the analyzed sample (N = 348), almost all women were married (94%), had attained a secondary level of education (71%), and were not formally employed (98%). Around 70% of women were younger than 33 years old; 35% resided under 4 km from the clinic; 53% of enrolled women were on ART at first ANC booking; 85% had disclosed their HIV status at booking suggesting selection bias in enrollment. Baseline characteristics of enrolled women were similar between the 2 trial arms except for education level and ART status at first booking; women from the intervention arm were proportionally less educated and more likely to be on ART than in the control arm (Table 2).

Primary Outcome

The proportion of infants retained in care in the intervention arm at 12 months was 69% (130/188) versus 61% (98/160) in the control arm, with no significant difference between the 2 arms—both before and after adjustment for mothers' baseline characteristics (Table 3). In multivariate analysis, 4 maternal covariates reached

significance for infant retention in care at 12 months of age: maternal age older than 32 years (compared with those younger than 28 years); living 4–7 km from the clinic (compared with those living closer than 3 km); being on ART at first ANC booking (compared with those not on ART at first booking); and had disclosed her HIV status to partner at enrollment (compared with those who had not disclosed) (Table 4). Examination of the number of consecutive 60-day periods with at least 1 visit at the clinic showed that 14% of babies never attended, 14% attended at least once during 5 periods, and 55% of babies attended at least once during each of 6 consecutive 60-day periods of follow-up.

Secondary Outcomes

The effect of the intervention did not reach significance for any secondary outcome: infants' regular attendance at clinic visits at 12 months (74% in control versus 80% in intervention arm); mothers' point attendance at the clinic at 12 months (61% versus 71%); mother's regular attendance at clinic visits (71% versus 78%); ANC visit dose (46% versus 52%); institutional delivery (75% versus 77%); family planning (65% versus 71%); final disclosure (96% versus 95%); infant testing (62% versus 72%); and immunization (66% versus 74%) were not significantly different between the arms (Table 3). Examination of the number of consecutive

TABLE 2. Baseline Characteristics of Pregnant Women Living With HIV

	Enrolled Women, n (%)			Assessment, n (%)			Assessed and Eligible Women, n (%)		
	Intervention (n = 188)	Control (n = 160)	P*	Assessed (n = 798†)	Nonassessed (n = 179†)	P*	Enrolled (n = 348)	Nonenrolled (n = 157†)	P*
Age, yr									
18–27	64 (34)	65 (41)	0.25	353 (44)	72 (40)	0.48	129 (37)	75 (48)	0.11
28–32	60 (32)	53 (33)		233 (29)	52 (29)		113 (33)	37 (23)	
33 and more	64 (34)	42 (26)		212 (27)	55 (31)		106 (30)	45 (29)	
Gestational age at first booking, wk									
2–15	73 (39)	61 (38)	0.99	256 (33)	50 (28)	0.02	134 (39)	50 (33)	0.24
16–21	60 (32)	52 (32)		240 (30)	42 (24)		112 (32)	54 (35)	
22–34	55 (29)	47 (29)		290 (37)	85 (48)		102 (29)	48 (32)	
Parity									
0–1	61 (32)	56 (35)	0.63	327 (41)	72 (40)	0.82	117 (34)	68 (43)	0.04
2–3	93 (50)	71 (44)		357 (45)	84 (47)		164 (47)	73 (47)	
3 and more	34 (18)	33 (21)		114 (14)	23 (13)		67 (19)	16 (10)	
Marital status									
Married	175 (93)	153 (96)	0.43	632 (92)	115 (91)	0.83	328 (94)	108 (87)	0.03
Not married	13 (7)	7 (4)		58 (8)	12 (9)		20 (6)	16 (13)	
Educational level									
None/primary	65 (35)	37 (23)	0.03	188 (31)	28 (32)	0.90	102 (29)	33 (33)	0.62
Second/tertiary	123 (65)	123 (77)		421 (69)	59 (68)		246 (71)	66 (67)	
Occupation‡									
Formally employed	3 (2)	5 (3)	0.56						
Not formally employed	185 (98)	155 (97)							
Religion‡§									
African Initiative Churches	82 (44)	54 (34)	0.18						
Apostolic sects	21 (11)	16 (10)							
Orthodox Christian	50 (27)	49 (31)							
Pentecostal	27 (14)	36 (22)							
None	8 (4)	5 (3)							
Distance from clinic, km									
0–3	73 (39)	48 (30)	0.19	208 (31)	27 (27)	0.03	121 (35)	40 (31)	0.27
4–7	59 (31)	62 (39)		244 (37)	28 (28)		121 (35)	57 (45)	
8 and more	56 (30)	50 (31)		212 (32)	45 (45)		106 (30)	31 (24)	
ART status at first booking									
On ART	111 (59)	75 (47)	0.03	362 (45)	70 (39)	0.15	186 (53)	60 (38)	0.00
Not on ART	77 (41)	85 (53)		435 (55)	109 (61)		162 (47)	97 (62)	
Disclosure to partner									
No	24 (13)	29 (18)	0.22						
Yes	164 (87)	131 (82)							

EPAZ trial (2014–2016).

*We used χ^2 tests to compare the distribution of baseline characteristics by the arm and by enrollment status. These tests ignore the effects of clustering in clinics.

†N are varying, as pairwise deletion was performed to take missing data into account.

‡Occupation and Religion were not available on 63 and 92%, respectively, for nonenrolled women, so no comparison was performed for these 2 variables.

§In next steps, Religion was recoded as Apostolic sects versus others, as they are known to be less favorable toward health care (24, 25).

||Disclosure was not available for nonenrolled women.

60-day periods with at least 1 visit at the clinic showed that 12% of mothers never attended, 20% attended at least once during 5 periods, and 46% attended at least once during each of 6 consecutive 60-day periods of follow-up.

Adverse Events

One adverse event was reported during the study. An enrolled mother in the intervention arm experienced domestic violence from her intimate partner after returning home later

than expected after an MSG meeting. The case was investigated, reported, and no further action was deemed necessary.

DISCUSSION

In this community-based trial in rural Zimbabwe, we were unable to show that MSGs improved retention in care at 12 months among HIV-exposed infants. Retention rates were around 65% and were comparable between the 2 arms. No statistically significant differences between arms were

TABLE 3. Comparison of Outcomes Between Intervention Arm (N = 188) and Control Arm (N = 160)

			Unadjusted Analysis			Adjusted Analysis*		
	Arm	Outcome n (%)	OR	95% Confidence Interval (CI)	P	aOR†	95% CI	P
Infant retention in care at 12 mo								
Point retention‡	Intervention	130 (69)	1.43	0.89 to 2.31	0.14	1.25	0.73 to 2.15	0.42
	Control	98 (61)	1.00	—		1.00	—	
Regular retention	Intervention	151 (80)	1.43	0.86 to 2.39	0.17	1.26	0.73 to 2.19	0.41
	Control	118 (74)	1.00	—		1.00	—	
Mother retention in care at 12 mo								
Point retention	Intervention	134 (71)	1.46	0.92 to 2.30	0.11	1.31	0.80 to 2.12	0.28
	Control	98 (61)	1.00	—		1.00	—	
Regular retention	Intervention	146 (78)	1.37	0.84 to 2.25	0.21	1.14	0.67 to 1.95	0.62
	Control	113 (71)	1.00	—		1.00	—	
Maternal and infant health indicators								
ANC dose	Intervention	97 (52)	1.27	0.78 to 2.07	0.34	1.31	0.78 to 2.18	0.31
	Control	73 (46)	1.00	—		1.00	—	
Delivery at a health facility	Intervention	145 (77)	1.14	0.67 to 1.94	0.62	1.17	0.65 to 2.11	0.59
	Control	120 (75)	1.00	—		1.00	—	
Family planning	Intervention	133 (71)	1.16	0.70 to 1.93	0.56	1.00	0.58 to 1.71	0.99
	Control	104 (65)	1.00	—		1.00	—	
Disclosure to partner	Intervention	179 (95)	0.82	0.28 to 2.38	0.72	0.36	0.06 to 2.25	0.28
	Control	154 (96)	1.00	—		1.00	—	
Infant testing	Intervention	126 (67)	1.45	0.64 to 3.27	0.37	1.38	0.59 to 3.24	0.46
	Control	99 (62)	1.00	—		1.00	—	
Immunization up to date	Intervention	140 (74)	1.50	0.89 to 2.54	0.13	1.40	0.74 to 2.66	0.30
	Control	105 (66)	1.00	—		1.00	—	

EPAZ trial (2014–2016).

*Adjusted analyses did not consider “Occupation,” as its distribution was highly unbalanced. “Parity” was also not considered, as it was highly correlated with age ($\chi^2(4) = 115.17$, $P < 0.001$).

†aOR = adjusted odds ratio.

‡For the primary outcome (Infants’ point retention), we checked for the interaction between the intervention/control variable and each of the 2 baseline variables unbalanced between the 2 arms (ART status at first booking and Level of education). The Arm * ART status interaction ($P = 0.18$) and the Arm * Education interaction ($P = 0.44$) did not reach significance and were not further considered. The ICC estimated by the method of the random intercept logistic model was 0.014.

observed concerning maternal retention in care or other program indicators, although rates were systematically higher in the intervention arm versus the control arm, suggesting trends toward positive health outcomes with exposure to MSGs. Other potential beneficial outcomes of attending MSGs such as well-being were not measured in the EPAZ study.

The intervention may have shown no significant impact due to selective enrollment of “low-risk” mothers. A substantial proportion (27%) of eligible women who were assessed did not consent to enroll in the study, possibly because of refusal due to the requirement for written consent. Women frequently reported requiring their partner’s approval before providing written consent. Most (85%) enrolled mothers had disclosed their HIV status to their partner at enrollment, although this was not a prerequisite for enrollment. No comparative data are available for nonenrolled mothers because disclosure status is not routinely recorded within PMTCT programs. Maternal HIV disclosure is frequently associated with increased ART initiation and adherence¹¹; women who joined the EPAZ study may have been more likely to have disclosed than nonenrolled women and thus be more likely to be retained. Women who were enrolled were also more likely than nonenrolled women to be married,

multiparous, or already established on ART, characteristics often associated with increased retention. A similar trends profile was also observed among women enrolled in the intervention arm and having regularly attended MSGs.¹⁹ Fear of discrimination may have deterred mothers newly established on ART from enrolling in the study and/or attending MSGs.¹¹ As a result of selective enrollment of women more likely to be retained in the study, the impact of the MSGs on retention and other program indicators may have been reduced for both mothers and infants.

Another reason that may explain reduced impact is that substantially fewer better-educated mothers enrolled in the intervention arm than the control arm. Results from a qualitative study conducted midtrial suggested that better-educated mothers were unwilling to associate with mothers perceived to be of inferior social standing.²⁰ Educational level is positively associated with increased retention in ART programs,²¹ and this may have led to reduced impact in our study. However, this effect may have been counter balanced by the fact that a higher proportion of women were already on ART at booking in the intervention arm compared with the control arm (59% versus 47%).

A third reason for lack of impact relates to factors inhibiting retention not addressed in this MSG model. During

TABLE 4. Multivariate Analysis for the Primary Outcome (Infant Point Retention in Care at 12 Months)

	Not Retained (n = 120)	Retained (n = 228)	Adjusted Odds Ratio	95% Confidence Interval	P
Intervention					
Control	62 (52)	98 (43)	1.00		0.42
Intervention	58 (48)	130 (57)	1.25	0.73 to 2.15	
Age, yr					
18–27	58 (49)	71 (31)	1.00		0.07
28–32	35 (29)	78 (34)	1.48	0.83 to 2.63	
33 and more	27 (22)	79 (35)	2.02	1.10 to 3.69	
Educational level					
None/primary	30 (25)	72 (32)	1.00		0.72
Secondary/ tertiary	90 (75)	156 (68)	0.91	0.52 to 1.57	
Distance from clinic, km					
0–3	50 (42)	71 (31)	1.00		0.01
4–7	33 (27)	88 (39)	2.46	1.34 to 4.52	
8 and more	37 (31)	69 (30)	1.57	0.86 to 2.89	
ART status at first booking					
Not on ART	78 (65)	84 (37)	1.00		0.00
On ART	42 (35)	144 (63)	2.67	1.58 to 4.51	
Disclosure to partner					
No	30 (25)	23 (10)	1.00		0.02
Yes	90 (75)	205 (90)	2.19	1.11 to 4.32	

EPAZ trial (2014–2016).

the formative research conducted before the trial²² and the midtrial project.²⁰ HIV-positive mothers and HCWs recommended that economic strengthening, transport, and material incentives (food, tee shirts, and umbrellas) be provided to mothers as part of the MSG intervention. Our model of MSG did not provide such incentives because these were not thought to be sustainable within public health facilities in Zimbabwe. Some studies suggest that providing incentives to patients can increase attendance and adherence to treatment for HIV and other diseases.^{23,24}

The lack of significant effects may be related to the sample size. The trial was designed as 80% powered to detect a 50% increase (50% in the control arm versus 75% in the intervention arm) in infant retention. Even with a reduced ICC, the sample size was likely not sufficient to detect the observed difference (61% versus 69%) as significant.

Another limitation of this study was our reliance on HCWs at clinics to conduct the study. They were responsible for collection of routine and additional study data, performing eligibility assessments, consenting and enrollment, and in intervention arm clinics, encouraging HIV-positive mothers to attend MSGs. Additional training and supervision was provided for HCWs through collaboration with district health teams. Small monetary incentives were provided to HCWs based on the quality of routine data collection with equal incentive scales for both arms. The data quality scheme led to

improvements in data quality. But with a median of 2.5 trained HCWs at each facility and competing demands on HCW time, it is unsurprising that substantial numbers of potentially eligible mothers were not assessed or did not enroll in the study. In addition, it is unclear how much HCWs in the intervention arm encouraged mothers to join the study or attend MSGs regularly, especially mothers who were at high risk and less motivated to engage in PMTCT programs.

A further limitation was that the study was implemented without nationally agreed definitions of retention indicators, a national monitoring system on retention in care, or a policy on identifying and tracing patients lost to follow-up or who default. Although Option B-plus has led to increased initiation of HIV-positive mothers on ART,²⁵ greater attention must be given to retention in care and adherence to treatment. MSG interventions may function more effectively if PMTCT program retention systems are functioning and monitored with nationally agreed indicators. Documenting HIV disclosure status and supporting disclosure by mothers to their partners by HCWs during the antenatal and postnatal periods are essential components of PMTCT programs, without which retention interventions may be less effective.

Despite these limitations, this study provided insights on the potential of MSGs to improve the health of HIV-exposed infants and their mothers through increased retention in care and other health outcomes. The study includes comprehensive data collection through a prospective study conducted in hard-to-reach rural populations. Substantial numbers of mothers belonged to religious minorities characterized by lack of health-seeking behaviors to modern health care.^{26,27}

The facility-based model of MSGs evaluated in the EPAZ trial differs from other PMTCT peer support models because expert mothers were unpaid volunteers.²⁸ The effectiveness of MSGs depended in this study on the motivation and involvement of clinic-based HCWs to encourage HIV-positive mothers to join MSGs and of district health team members to train and supervise mothers in their new responsibilities. The adoption of this MSG model by health providers could increase the impact of the intervention on retention by ensuring that trained HCWs actively and repeatedly recruit HIV-positive mothers into MSGs, especially high-risk mothers who are younger, newly diagnosed, primipara, single or who book late for ANC. At the conclusion of this study, meetings were held with local and national health implementers and policymakers to discuss expansion of the EPAZ MSG model to other sites in Zimbabwe, incorporating modifications to more effectively reach newly diagnosed and other high-risk mothers.

Two newer understandings around HIV provide reasons why MSGs could play important roles in future national PMTCT strategies. As PMTCT coverage expands, the number of HIV-infected children is declining. Greater attention is being given to increasing numbers of HIV-exposed, uninfected children (HEU) in view of their impaired growth, increased morbidity, and excess mortality. Closer monitoring of HEU with an increased frequency of clinic visits has been proposed as a measure to improve their

health,^{29,30} and MSGs have a potential to support this strategy.³¹ Community ART refill groups, currently implemented by MOHCC and shown to be efficient in other regions of southern Africa, have been found to improve retention in care.^{32,33} MSGs are well placed to support and strengthen both of these strategies. Further studies to assess whether peer support, MSGs, or other expert mother initiatives in PMTCT programs can lead to increased HIV-free survival rates of HEU and strengthen newly established community ART refill group programs.

The MSGs evaluated in the EPAZ trial were led by volunteer mothers from the community and based in MOHCC clinics. Greater health sector engagement with MSGs could enhance their effectiveness and increase retention in PMTCT care. The integration of MSGs into standard-of-care provision would provide HCWs with a powerful peer-led intervention that could support high-risk HIV-positive mothers who are less likely to be retained in care.

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