Home Visits During Pregnancy Enhance Male Partner HIV Counseling and Testing in Kenya: A Randomized Clinical Trial

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Abstract

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Background

HIV testing of male partners of pregnant women is important to decrease HIV transmission to women and to support HIV-infected women in taking prevention of mother-to-child HIV transmission (PMTCT) interventions. However, it has been difficult to access male partners in antenatal care (ANC) settings. We hypothesized that home visits to male partners of women attending ANC would be feasible and would increase HIV testing of partners.

Methods

Pregnant women attending ANC were enrolled, interviewed using smartphone audio-computer assisted self-interviews (ACASI), and randomized to home visits or written invitations for male partners to come to clinic. Enrolled men were interviewed (ACASI) and offered couples HIV counseling and testing (CHCT). Participants underwent follow-up ACASI six weeks post-enrollment. Prevalence of CHCT, male HIV, couple discordance, intimate partner violence were compared using intent-to-treat analysis.

Results Among 495 women screened, 312 (63.0%) were eligible, of whom 300 were randomized to clinic-based or home-based HCT. Median age was 22 years [interquartile range (IQR) 20,26]; most were monogamous (87%) and 11% reported condom use and did not differ between trial arms. Male CHCT was substantially and significantly higher in the home-visit than the clinic-invitation arm (87% vs. 36%, $p<0.0001$). A higher proportion of women in the home-visit than clinic-invitation arm reported improved relationship quality 6 weeks after CHCT (70% vs. 29%, $p<0.0001$) and there was no increased risk of intimate partner violence or relationship instability.

Conclusion Home visits were safe, acceptable, and resulted in more pregnant women and their male partners learning each other's HIV status. This strategy could facilitate efforts to prevent HIV acquisition among pregnant women, improve PMTCT uptake, and accelerate male HIV diagnosis and linkage to care.

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DEDICATION

This work is dedicated to my family Monicah, Randy and Rowley for their love, understanding, support and challenge to improve on my performance.

INTRODUCTION

In developing countries, especially in sub-Saharan Africa, the male partner may strongly influence decisions affecting women's reproductive health and uptake of prevention of mother-to-child HIV transmission (PMTCT) interventions [1-4]. Women who undergo individual HIV counseling and testing (HCT) without male partner support may not disclose their HIV status to their partner due to fear of accusations of infidelity, violence, abandonment, and loss of economic support [5, 6]. Women who do not secure their male partners' support are less likely to adhere to comprehensive PMTCT interventions [7, 8]. Lack of male partner HIV testing among serodiscordant couples may also result in maternal HIV seroconversion during pregnancy and breastfeeding if the man is HIV infected, and these acutely infected women are at exceptionally high risk of MTCT [9, 10]. However, although couple HCT may increase uptake of PMTCT, male partner HCT remains low [11-13].

Increasing male partner involvement has been stymied by inability to access male partners of pregnant women in antenatal care (ANC) clinics. Less than 20% of male partners undergo clinic-based HCT in most low–resource settings, even following adaptations to the clinic to encourage male attendance [8, 13, 14]. One study noted increased uptake of male partner testing following community mobilization and sensitization, and written invitation but this was only a modest increase (to 32%) [15]. Barriers to male testing in ANC include inadequate infrastructure within the ANC clinics and cultural norms that view ANC clinics as limited to women [2, 3, 16, 17].

Innovative approaches of reaching male partners for couple HCT during pregnancy and increasing male partner involvement are therefore desperately needed, in order to accelerate progress towards elimination of MTCT. This is more important since the global target to reduce new annual pediatric HIV infections from the 2009 estimate of 370,000 to fewer than 40,000 by 2015 remains elusive [18]. Whereas Kenya witnessed a 43%

decrease in new HIV pediatric infections from an estimated 23,200 in 2009 to approximately 13,200 in 2011, which is more than in many parts of sub-Saharan Africa, it is inadequate progress towards elimination of mother-to-child HIV transmission (MTCT) by 2015 [6, 19, 20].

In regions with high HIV prevalence, community-wide door-to-door home-based HIV counseling and testing (HBCT) has been feasible and leads to increased uptake of HIV testing [22, 23]. However, in at least three studies, less than 30% of testers reached through door to door HBCT were men and very few (~4%) of the tested men were partners of women who were pregnant at the time of male testing [21-23]. It is unknown whether provider-initiated home-based couple HCT offered to women attending ANC clinics would be acceptable and effective in increasing male partner HCT. To evaluate whether home visits would increase male partner involvement among pregnant women attending ANC, we conducted a randomized clinical trial to compare male partner access and uptake of couple HCT between pregnant women visited at home and those whose partners were invited to the clinic.

METHODS

Study design and setting This was a randomized single blind clinical trial in which pregnant women seeking prenatal care underwent block randomization to either immediate home visit or invitation to bring their male partner to the clinic for couple HIV counseling and testing. The study was conducted in a rural resource-constrained setting in Nyanza province, Kenya at the Ahero sub-district Hospital. The hospital provides PMTCT services as well as comprehensive HIV care within the facility, including antiretroviral therapy. Nyanza has HIV prevalence of 13.9%, which is more than twice the national average of 6.3% [24]. A recent multisite national study also reported higher incident maternal HIV infection in Nyanza compared to all other sites (13.8 versus 6.8 per 100 woman-years [9].

Study procedures All pregnant women presenting at the clinic for their first ANC visit were screened for study eligibility. Women were eligible if they were ≥18 years old and unaccompanied by their male partners during their first ANC visit. Eligible women could not have received couple HCT in the current pregnancy, prior to their first ANC visit. HIV positive women were ineligible if they had previously disclosed their HIV status to their partner. Women were enrolled if they understood and consented for randomization to a home or clinic visit for proposed couples HCT, and planned to stay in the study area for at least 6 weeks.

Eligible women were enrolled after written informed consent and interviewed through Audio Computer Assisted Self Interview (ACASI), received HCT and then randomized. Women were randomized in a ratio of 1:1 and blocks of 20 to either immediate home visit or to clinic-invitation to bring their partner to clinic for couple HCT. A trained community health worker, who was also an experienced HIV counselor, immediately accompanied women who were randomized to the home HCT arm to their homes to access the male partner and invite his participation in the study. If the male partner was not available or not able to be enrolled until a later date, an appointment was scheduled. The counselors obtained home physical address and global positioning system (GPS) coordinates for return visits.

Pregnant women allocated to the clinic-based arm were given a written note inviting their male partners for reproductive health education and couple HCT at the ANC clinic and they also provided details of their home physical address. Women in the clinic HCT arm were encouraged to schedule appointments for themselves and their partner or walk in on any clinic day for couple HCT. In both arms, if the man had not been reached two weeks after the enrollment of the woman, a one-time phone call and/or text message reminder

was made to the woman to reschedule appointments.

In both trial arms, male partners were enrolled after providing written informed consent and individually interviewed (ACASI) and then offered couple HCT. Male partners were considered not reachable if they had not been traced by the time the pregnant women were due for follow-up.

HIV counseling and testing were conducted according to Kenya National HIV AIDS and STIs Control Programme guidelines for prenatal and couple HCT. Women's HIV status was known to the woman and the provider following the enrollment visit but was only disclosed to their male partner after both had undergone couple HCT.

A 6-week follow-up visit either at home or at the clinic, as preferred by individual participant, was conducted to assess relationship status. Participants were reminded of their follow-up dates two weeks prior to the appointment through a phone call and short text message. Subjects were traced through the cell phones contacts or home visits using the GPS coordinates and/or physical address. Loss to follow-up occurred if participants were not reached two weeks after their scheduled follow-up date.

Audio computer assisted interviews (ACASI) Study counselors demonstrated to each study participant the correct use of the smartphone for self-interview prior to randomization and HCT. Pregnant women underwent individual ACASI in a private room at the clinic following enrolment and prior to HCT. Male partners underwent ACASI at the clinic while those enrolled at home were interviewed at a private location within their homes. The interviews were conducted in the preferred language, either English or Dholuo (the local dialect), on sociodemographics, reproductive health decisions, HIV risk factors, and uptake of HIV prevention interventions. At follow-up, participants were interviewed on stability of their relationships and intimate partner violence.

Randomization and blinding An independent statistician used a computer-generated list of random numbers using Stata 11.0 (StataCorp, College Station, TX) statistical software in random blocks of 20 and a ratio of 1:1 to allocate study arms. The randomly generated numbers were contained in opaque sealed envelopes sequentially numbered with participant study identification numbers. The study staff used the random numbers as barcodes and scanned them to countercheck their matching with participant study identification numbers. The independent statistician was then called to issue the study arm corresponding to the barcode.

The principal investigator and data analysts were blinded to the study arm. The study counselors and women were unaware of the randomization assignment during enrollment, interviews and HCT. Post randomization, it was not practical to blind the counselors and study participants due to the nature of the study. Participating men adhered to the study arm the pregnant women were randomly assigned to. At follow-up pregnant women and their male partners were interviewed at their preferred venue, home or clinic.

Sample size To detect a 50% increase in male partner tracing and uptake of couple HCT between the invited men and those visited at home, we determined that an enrollment of 268 pregnant women (134 per study arm) would provide at least 80% power to detect this difference between groups at a two-sided 5% level of significance. For an estimated 10% loss to follow up, we increased our sample size to 300.

Statistical analysis Smartphone (Google Nexus S) ACASI data was checked for inconsistencies and saved on an Open Data Kit (ODK) collect form, then downloaded and submitted to ODK aggregate where it was stored in the database daily. Smartphones and paper data backup were securely stored. Stored data were exported from an ODK aggregate into a CSV file and imported into a Stata (800-STATA-PC, College Station, Texas) database for a pre-planned statistical data analysis using Stata 12. The primary analysis was

conducted on an intention-to-treat basis and included all randomized pregnant women. The proportions of men who were interviewed and underwent couple HCT were compared between the two study arms using Chi-square test with two tailed t-tests. Baseline characteristics, including HIV prevalence by gender, couple serodiscordance, and intimate partner violence were compared between the study groups. During follow-up, the prevalence of relationship stability and changes in intimate partner violence were determined and compared between the study groups.

Ethical Statement

The Ethical Review Committee of Kenyatta National Hospital and the University of Nairobi, and the University of Washington's Institutional Review Board, approved the study protocol. All study participants provided written informed consent in either the local language (Dholuo) or English.

Study oversight

The study was supported by the Fogarty International Center through the International AIDS Research and Training Program, University of Washington. The community advisory board provided oversight and advice. The primary author is responsible for the completeness and accuracy of the data presented, as well as the adherence of this report to the study protocol. The study protocol adhered to the consort guidelines and was registered at ClinicalTrials.gov, registration number, NCT01620073.

RESULTS

Population characteristics

Between July 2012 and February 2013, 495 women attending their first ANC visit were screened. Of the eligible 312 (63%) pregnant women, 300 (96.2%) were randomly assigned to the clinic-based (n=150) and home-based (n=150) groups (Figure 1). Among 183 ineligible women, reasons for ineligibility included: known HIV positive prior to current pregnancy (n=53), not planning to be in the area for six weeks (n=32), single students or separated with no stable partner (n=72), widow (n=2), visitors or non-residents (n=8), already presented with their male partners or had previously undergone couple HCT in their current pregnancy (n=14) and a negative urine pregnancy test (n=2). Twelve (3.8%) of the eligible women were not enrolled either because they wanted to consult their male partners (n=5), were in a hurry to get home (n=4) or were participating in another study (n=3).

The two groups had similar baseline characteristics (Table 1). The median age of women was 22 years (interquartile range 20, 26), and 95.7% were married of whom 91.3% were in monogamous partnerships. About two-thirds (67.3%) had primary or lower while about one tenth (12%) reported post-secondary level as the highest level of education. Most women had an estimated daily income of <$2. The majority of the women (74.3%) reported daily use of cell phones. During enrolment, 51 (17.0%) of women were primigravida. Less than half (44%) of participating women reported previous contraceptive use and majority (95%) used hormonal contraception. Whereas a substantial number of women (28.7%) perceived that their male partners had concurrent sexual relationships only 8 (2.7%) of the women reported that they had concurrent sexual partnerships. At enrollment, 25.0% of women had experienced a physical threat from their male partner while 2.7% experienced forced sex over the preceding six months. Most women (96%) expressed willingness to use pre-exposure prophylaxis and antiretroviral treatment for HIV

prevention. Although interest in voluntary male medical circumcision of male partner was high among women, (>70%), only one-in-three men were reported by female partners to be circumcised, and self-reported condom use in the past month was low (<15%). Overall, 48 (16%) of the randomized women were HIV positive, 21(14%) in the home-based arm and 27(18%) in the clinic-based arm.

Male partner access and uptake of couple HIV counseling and testing

Male partners in the home-visit arm were more likely to be reached (89% vs. 37%, p<0.0001) and to receive couple HCT (85% vs. 36%, p<0.0001). Thus, male partners were significantly more than twice as likely to be reached (relative risk [RR] 2.42; 95% confidence interval [CI] 1.94-3.01), and to undergo couple HCT at home (RR 2.37; 95% CI 1.90–2.96) using the provider-initiated home HCT strategy compared to ANC clinic invitation (Table 2). Overall, 18 (12%) of the male partners of women randomized to the home arm were HIV positive compared to 12 (8%) of those randomized to the clinic arm. Women were two and a half times as likely to have their male partner test HIV negative at home than the clinic (73.3% versus 28.0% respectively, RR 2.62 95% CI 1.99 3.45, p<0.0001. Significantly more couples were likely to be concordant negative if tested at home (66.0%) compared to the clinic (26.0%), RR 2.53 (1.89-3.40), P<0.0001, and similar proportions were concordant positive (4.7% at home versus 5.3% at the clinic). Couples were thrice as likely to be HIV serodiscordant at home (14.7%) than clinic (4.7%) RR, 3.14 [1.38-7.13], p=0.003, and less likely to have undetermined couple HIV status at home (14.7%) compared to the clinic (64.0%), RR 0.23 [0.15-0.34], P<0.001.

The HIV prevalence among male partners tested at home was 14.1% (18 of 128) compared to 22% (12 of 54) of those tested at the clinic. Participants who underwent couple HCT had HIV serodiscordance of 15.9%, 17.2% at home and 13% at the clinic.

Among couples who underwent HCT, those tested at home were 63% less likely be HIV concordant positive (5.5%) than those tested at the clinic (14.8%), RR 0.37 [0.14-0.97], p=0.036. Similar proportions, 77.3% of those who underwent couple HCT at home and 72.2% of those tested at the clinic were concordant HIV negative, and serodiscordance did not vary by study arm (17.2% at home versus 13.0% at the clinic. Married women were substantially and significantly more likely to be tested at home if their relationships were polygamous (RR 5.96 [1.65-21.56] than monogamous (RR 2.18 [1.74-2.73].

Intimate partner violence and relationship stability

In both arms, reports of physical threats from male partners at follow up did not vary markedly from those at baseline, 14.7% at home compared to 17.3% at the clinic (Table 2). At 6-week follow-up, 2% of women associated the physical threat to couple HCT in each arm. The experience of forced sex was less prevalent at follow-up, 0.01% of women in the home arm and none in the clinic arm reported forced sex (Table 2). Two women who separated from their male partners, one in each study arm, were traced, provided with marital counseling and reunited with their male partners by follow-up. Improved qualities of relationships were more than twice as likely to be reported among women whose partners were tested at home (69.9%), than those whose partners were tested at the clinic (28.9%), (RR 2.35; 1.78- 3.09; p<0.001). Relationships were also less likely to be the same among couples tested for HIV as couples at home (28.9%) compared to those tested at the clinic (66.9%), RR 0.43 95% CI 0.33-0.57, p<0.001. Women who experienced worsening quality of relationships did not differ my randomization arm, 4% at home versus 5% at the clinic. One woman separated from her male partner for social reasons not related to couple HCT and was lost to follow-up.

DISCUSSION

In this randomized clinical trial, among pregnant women seeking antenatal care in a high HIV prevalence setting, a strategy of home-visit for couples HCT more than doubled the number of male partners reached and tested for HIV. The 85% male partner access and couple HIV counseling and testing (HCT) found in this study is the highest reported for male partners of pregnant women and substantially higher than that reported in previous studies that used community mobilization, written invitations, couple-oriented post-test HIV counseling or home based door-to-door HCT [15, 21, 25, 26]. There was high acceptability of provider-initiated home visits for couple HCT most likely due to prior door-to-door HBHT in the region, experience and flexibility of the counselors, and the couples HCT testing approach which provided for confidentiality and sharing of results between partners. Provider-initiated home visits may overcome the challenges of male partner access and couple HCT, increase male partner involvement and lead to improved uptake of PMTCT and enhanced infant HIV-free survival, increase detection of male HIV infection, accelerate access to treatment, and contribute to HIV prevention among women at risk [27]. In addition, male partner access and involvement may improve other maternal and child health outcomes such as skilled attendance at delivery and under-five mortality.

Intriguingly, couples in the clinic visit arm were more likely to be concordant positive than those in the home-visit arm and less likely to be HIV discordant, suggesting that HIV-infected males or couples who suspected or knew their own HIV infection were more likely to come to clinic while the home visit captured more couples including those in which risk was less perceived. This is a key finding since serodiscordant couples are at high risk of heterosexual HIV transmission and maternal seroconversion rates substantially increases the risk of MTCT [10, 28-30]. Among HIV serodiscordant couples where the man is HIV positive, early initiation of antiretroviral therapy can reduce sexual transmission, maternal seroconversion and MTCT [31]. By identifying more serodiscordant couples, provider-

initiated home-based couple HCT during pregnancy may have the potential to decrease maternal HIV infection. In contrast to other interventions, such as antiretroviral pre-exposure prophylaxis have been minimally evaluated in pregnant/postpartum women due to concerns regarding fetal/infant safety, partner antiretroviral therapy (ART) is an immediately implementable intervention to prevent maternal HIV during this risk period. In addition, home-based HCT may also reduce the high female-male heterosexual transmission during pregnancy because the male partner may support maternal uptake of ART and consistent use of condoms [30].

In this study, more men were newly diagnosed as HIV positive at home and referred for HIV care. Studies show that men are less likely to undergo HCT and more likely to present late for ART [32, 33]. Home visits for couple HCT during pregnancy may increase prompt HIV diagnosis and encourage early treatment of HIV positive men. Early antiretroviral therapy may also lower community and population HIV viral load and further reduce the risk of HIV transmission[34].

This study did not find increased risk of intimate partner violence or relationship instability among couples 6 weeks post-randomization. This is consistent with other studies that have not found increased risk of partner violence or relationship dissolution following couple HCT [15, 25, 35]. In fact, during follow-up, more women reported improved relationships following home-based couple HCT than clinic based HCT. Provider-initiated antenatal home visits for couple HCT during pregnancy were safe and did not negatively impact stable relationships. Programs and larger studies in other populations should continue to monitor any adverse intimate partner violence and relationship outcomes to confirm these findings.

In addition to being a randomized trial, our study had several strengths, as well as a few limitations. The study was conducted in a rural setting where HIV prevalence is high

and socioeconomic status is low, and this increases its generalizability to other parts of sub-Saharan Africa that are hard-hit by the HIV epidemic. Second, the intervention was conducted after women had received antenatal care and did not interfere with other antenatal care activities. Therefore, implementing home visit for couple HCT may not require major programmatic changes. Another strength is that we achieved high follow-up rates that enabled a comprehensive evaluation of short-term outcomes. This may have resulted from male partner support, suggesting that home-based approach to couple HCT during pregnancy can improve short-term adherence. Our study limitation included the fact that it excluded women in unstable relationships whose risk of incident sexual and vertical HIV transmission could be speculated to be higher. This did not markedly limit generalizability of our findings because these women were in the minority, and a majority of participating women were in stable relationships. More importantly, due to the short follow-up period, the study did not address long-term outcomes including incident maternal HIV infection, linkage to care for men and women, other maternal and child health outcomes, and intervention's cost effectiveness. These should be addressed in studies with longer durations of follow-up, which will provide valuable information for scaling up this intervention and assessing additional benefits to women, men and children.

In summary, in this randomized controlled study, home visits during pregnancy were safe, acceptable, feasible, and significantly increased the number of male partners who underwent couple HCT. As a strategy provider-initiated home visits for couple HCT during pregnancy could have a major public health impact and contribute to the elimination of MTCT through enhanced uptake of PMTCT especially in high HIV prevalence and low-resource settings. In addition, it may have the potential to improve other maternal, child, and male partner health outcomes.

Figure 1: Enrollment and follow-up of pregnant women seeking prenatal care

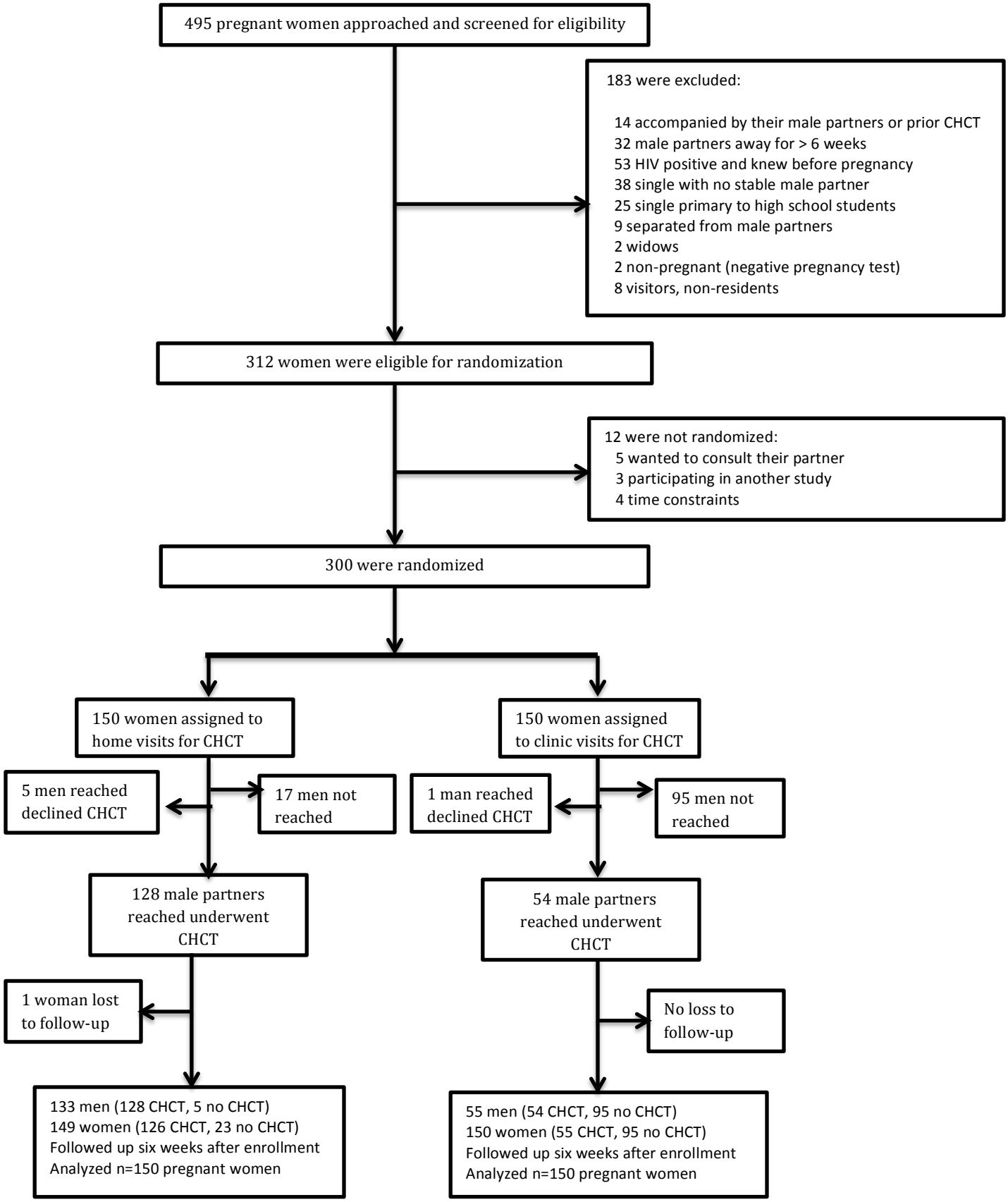


Table 1. Baseline characteristics of enrolled pregnant women by study arm

Characteristic		Home-based visits N=150		Clinic-based visits N=150	
Age (years)					
	Median	22		22	
	Interquartile range	20,25		20,26	
Age (years) - no (%)					
	Above median	83	(55.3)	83	(55.3)
	≤25	103	(68.7)	102	(68.0)
	>25	47	(31.3)	48	(32.0)
HIV status					
	HIV positive	21	(14.0)	27	(18.0)
Highest education level -no (%)					
	Primary or lower	103	(68.7)	99	(66.0)
	Secondary (some or complete)	39	(26.0)	41	(27.3)
	Post secondary	8	(5.3)	10	(6.7)
Marital status					
	Monogamous	131	(87.3)	131	(87.3)
	Polygamous	12	(8.0)	13	(8.7)
	Unmarried (Single, widow or cohabiting)	7	(4.7)	6	(4.0)
Number of previous pregnancies					
	0	21	(14.0)	30	(20.0)
	1	45	(30.0)	41	(27.3)
	≥2	84	(56.0)	79	(52.7)
Contraceptive use prior to current pregnancy					
	None	85	(56.7)	83	(55.3)
	Hormonal	61	(40.7)	63	(42.0)
	Withdrawal, condom, sterilization	4	(2.7)	4	(2.7)
Economic status					
	Daily household income ≥$2	37	(24.7)	39	(26.0)
	Daily cell phone use	107	(71.3)	116	(77.3)
	Any computer use	21	(14.0)	23	(15.3)
Condom use					
	Any condom use past month	14*	(9.3)	18	(12.0)
	Missing	0	(0.0)	2	(1.3)
Sexual partnerships					
	Perceived partner concurrency	46	(30.7)	40	(26.7)
	Casual sex when away from partner	2	(1.3)	3	(2.0)
Physically threatened past 6 months					
	None	101	(67.3)	107	(71.0)
	Study partner	34	(22.7)	36	(24.0)
	Other partner or family member	15	(10.0)	4	(4.6)
Experienced forced sex					
	None	144	(96.0)	146	(97.3)
	Study partner	5	(3.3)	3	(2.0)
	Family member	1	(0.7)	1	(0.7)
Male circumcision					
	Supports VMMC	116	(77.3)	120	(80.0)
	Partner undergone circumcision	47	(31.3)	51	(34.0)

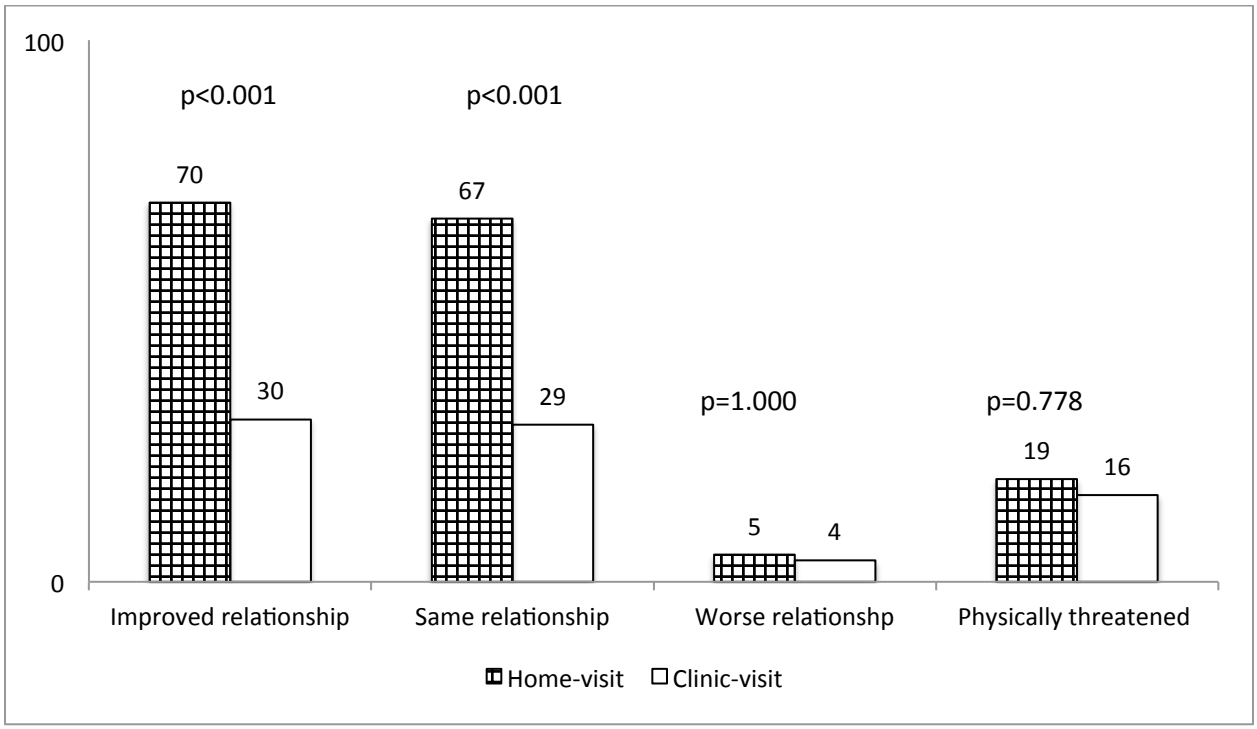
* 2 missing values, $ United States dollars, VMMC= voluntary male medical circumcision

Table 2 Male partner access, HIV counseling and testing and relationship status

Variable	Home visits		Clinic visits		RR	95%CI	P value
Overall male partner tracing and couple HIV testing							
Male partners reached	133/150	(88.7)	55/150	(36.7)	2.42	1.94-3.01	<0.001
Male partners tested	128/150	(85.3)	54/150	(36.0)	2.37	1.90-2.96	<0.001
Male partner HIV status							
Male partner HIV positive of overall partners including those not reached or tested							
Male partner HIV positive	18/150	(12.0)	12/150	(8.0)	1.5	0.74-3.00	0.248
Male partner HIV negative	110/150	(73.3)	42/150	(28.0)	2.62	1.99-3.45	<0.001
Male partner HIV positive of those HIV tested	18/128	(14.1)	12/54	(22.2)	0.63	0.33-1.22	0.175
Female HIV positive	21/150	(14.0)	27/150	(18.0)	0.67	0.34-1.34	0.345
Couple HIV status							
Overall couple HIV status among all couples including those not reached or tested							
HIV concordant negative	99/150	(66.0)	39/150	(26.0)	2.53	1.89-3.40	<0.001
HIV concordant positive	7/150	(4.7)	8/150	(5.3)	0.88	0.33-2.35	0.791
HIV discordant	22/150	(14.7)	7/150	(4.7)	3.14	1.38-7.13	0.003
Couple HIV status unknown	22/150	(14.7)	96/150	(64.0)	0.23	0.15-0.34	<0.001
Couple HIV status among the subset who had couple HIV counseling and testing							
HIV concordant negative	99/128	(77.3)	39/54	(72.2)	1.07	0.89-1.30	0.461
HIV concordant positive	7/128	(5.5)	8/54	(14.8)	0.37	0.14-0.97	0.036
HIV discordant	22/128	(17.2)	7/54	(13.0)	1.33	0.60-2.92	0.477
Relationship status at 6 weeks post-randomization							
Physically threatened in the past six months	22/150	(14.7)	26/150	(17.3)	0.85	0.50-1.42	0.529
Physically threatened due to couple testing	3/150	(2.00)	3/150	(2.00)	1.0	0.21-4.88	1.000
Worsened relationship since enrollment	6/150	(4.00)	7/150	(5.00)	0.86	0.29-2.49	0.778
Improved relationship since enrollment	100/141*	(69.9)	42/143†	(29.8)	2.35	1.78-3.09	<0.001
Same relationship status since enrollment	43/150	(28.9)	99/150	(66.9)	0.43	0.33-0.57	<0.001
Forced sex since enrollment	2/150	(0.01)	0/150	(0.00)	.	.	0.156

RR=Relative risk, CI=confidence interval, *9 missing values, †7 missing values

Figure 2: Relationship status of participating women at follow-up



REFERENCES

1. UNICEF. *State of the world's children*. New York: United Nations Children's Fund.
2. Bajunirwe F, Muzoora M. Barriers to the implementation of programs for the prevention of mother-to-child transmission of HIV: a cross-sectional survey in rural and urban Uganda. *AIDS Res Ther* 2005,**2**:10.
3. Kebaabetswe PM. Barriers to participation in the prevention of mother-to-child HIV transmission program in Gaborone, Botswana a qualitative approach. *AIDS Care* 2007,**19**:355-360.
4. Sarker M, Sanou A, Snow R, Ganame J, Gondos A. Determinants of HIV counselling and testing participation in a prevention of mother-to-child transmission programme in rural Burkina Faso. *Trop Med Int Health* 2007,**12**:1475-1483.
5. Medley A, Garcia-Moreno C, McGill S, Maman S. Rates, barriers and outcomes of HIV serostatus disclosure among women in developing countries: implications for prevention of mother-to-child transmission programmes. *Bull World Health Organ* 2004,**82**:299-307.
6. World Health Organization., UNICEF, UNAIDS, United Nations Population Fund. *Towards the elimination of mother-to-child transmission of HIV : report of a WHO technical consultation, 9-11 November 2010, Geneva, Switzerland*. Geneva: World Health Organization; 2011.
7. Peltzer K, Mlambo M, Phaswana-Mafuya N, Ladzani R. Determinants of adherence to a single-dose nevirapine regimen for the prevention of mother-to-child HIV transmission in Gert Sibande district in South Africa. *Acta Paediatr* 2010,**99**:699-704.
8. Farquhar C, Kiarie JN, Richardson BA, Kabura MN, John FN, Nduati RW*, et al.* Antenatal couple counseling increases uptake of interventions to prevent HIV-1 transmission. *J Acquir Immune Defic Syndr* 2004,**37**:1620-1626.

9. Kinuthia. *Co-factors for HIV incidence during pregnancy and the postpartum period.* Seventeenth Conference on Retroviruses and Opportunistic Infections , San Francisco, abstract 155, 2010. In; 2010.

10. Moodley D, Esterhuizen TM, Pather T, Chetty V, Ngaleka L. High HIV incidence during pregnancy: compelling reason for repeat HIV testing. *AIDS* 2009,**23**:1255-1259.

11. Auvinen J, Suominen T, Välimäki M. Male participation and prevention of human immunodeficiency virus (HIV) mother-to-child transmission in Africa. *Psychol Health Med* 2010,**15**:288-313.

12. Byamugisha R, Åstrøm AN, Ndeezi G, Karamagi CA, Tylleskär T, Tumwine JK. Male partner antenatal attendance and HIV testing in eastern Uganda: a randomized facility-based intervention trial. *J Int AIDS Soc* 2011,**14**:43.

13. Msuya SE, Mbizvo EM, Hussain A, Uriyo J, Sam NE, Stray-Pedersen B. Low male partner participation in antenatal HIV counselling and testing in northern Tanzania: implications for preventive programs. *AIDS Care* 2008,**20**:700-709.

14. Semrau K, Kuhn L, Vwalika C, Kasonde P, Sinkala M, Kankasa C*, et al.* Women in couples antenatal HIV counseling and testing are not more likely to report adverse social events. *AIDS* 2005,**19**:603-609.

15. Mohlala BK, Boily MC, Gregson S. The forgotten half of the equation: randomized controlled trial of a male invitation to attend couple voluntary counselling and testing. *AIDS* 2011,**25**:1535-1541.

16. Nkuoh GN, Meyer DJ, Tih PM, Nkfusai J. Barriers to men's participation in antenatal and prevention of mother-to-child HIV transmission care in Cameroon, Africa. *J Midwifery Womens Health* 2010,**55**:363-369.

17. Ditekemena J, Koole O, Engmann C, Matendo R, Tshefu A, Ryder R*, et al.* Determinants of male involvement in maternal and child health services in sub-Saharan Africa: a review. *Reprod Health* 2012,**9**:32.

18. UNAIDS. Global report: UNAIDS report on the global AIDS epidemic 2012 In; 2012.

19. UNAIDS. *Global report: UNAIDS report on the global AIDS epidemic 2010*. Geneva: UNAIDS; 2010.

20. Curran K, Baeten JM, Coates TJ, Kurth A, Mugo NR, Celum C. HIV-1 prevention for HIV-1 serodiscordant couples. *Curr HIV/AIDS Rep* 2012,**9**:160-170.

21. Naik R TH, Doherty T, Zembe W, Jackson D. **Client characteristics and acceptability of a home-based HIV counselling and testing intervention in rural South Africa.** In. BMC Public Health. 2012 Sep 25;12:824.; 2012 Sep 25.

22. JN S, H S, J L, MA M, S A, X Y*, et al.* **High acceptance of home-based HIV counseling and testing in an urban community setting in Uganda.** In: BMC Public Health. 2011 Sep 26;11:730. doi: 10.1186/1471-2458-11-730.; 2011.

23. Mulogo EM, Abdulaziz AS, Guerra R, Baine SO. Facility and home based HIV Counseling and Testing: a comparative analysis of uptake of services by rural communities in southwestern Uganda. *BMC Health Serv Res* 2011,**11**:54.

24. Macro. KNBoSKaI. *Kenya Demographic and Health Survey 2008/09.* Calverton, Maryland: Kenya National Bureau of Statistics (KNBS) and ICF Macro; 2010. In; 2010.

25. Orne-Gliemann J, Balestre E, Tchendjou P, Miric M, Darak S, Butsashvili M*, et al.* Increasing HIV testing among male partners. The Prenahtest ANRS 12127 multi-country randomised trial. *AIDS* 2013.

26. Bateganya M, Abdulwadud OA, Kiene SM. Home-based HIV voluntary counselling and testing (VCT) for improving uptake of HIV testing. *Cochrane Database Syst Rev* 2010:CD006493.

27. Aluisio A, Richardson BA, Bosire R, John-Stewart G, Mbori-Ngacha D, Farquhar C. Male antenatal attendance and HIV testing are associated with decreased infant HIV infection and increased HIV-free survival. *J Acquir Immune Defic Syndr* 2011,**56**:76-82.

28. Kinuthia J, Kiarie JN, Farquhar C, Richardson B, Nduati R, Mbori-Ngacha D*, et al.* Cofactors for HIV-1 incidence during pregnancy and postpartum period. *Curr HIV Res* 2010,**8**:510-514.

29. Munjoma MW, Mhlanga FG, Mapingure MP, Kurewa EN, Mashavave GV, Chirenje MZ*, et al.* The incidence of HIV among women recruited during late pregnancy and followed up for six years after childbirth in Zimbabwe. *BMC Public Health* 2010,**10**:668.

30. Mugo NR, Heffron R, Donnell D, Wald A, Were EO, Rees H*, et al.* Increased risk of HIV-1 transmission in pregnancy: a prospective study among African HIV-1-serodiscordant couples. *AIDS* 2011,**25**:1887-1895.

31. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N*, et al.* Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011,**365**:493-505.

32. Lahuerta M, Lima J, Nuwagaba-Biribonwoha H, Okamura M, Alvim MF, Fernandes R*, et al.* Factors associated with late antiretroviral therapy initiation among adults in Mozambique. *PLoS One* 2012,**7**:e37125.

33. Ndawinz JD, Chaix B, Koulla-Shiro S, Delaporte E, Okouda B, Abanda A*, et al.* Factors associated with late antiretroviral therapy initiation in Cameroon: a representative multilevel analysis. *J Antimicrob Chemother* 2013.

34. Das M, Chu PL, Santos GM, Scheer S, Vittinghoff E, McFarland W*, et al.* Decreases in community viral load are accompanied by reductions in new HIV infections in San Francisco. *PLoS One* 2010,**5**:e11068.

35. Kiarie JN, Farquhar C, Richardson BA, Kabura MN, John FN, Nduati RW*, et al.* Domestic violence and prevention of mother-to-child transmission of HIV-1. *AIDS* 2006,**20**:1763-1769.