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The Impact of a Couple-Based Intervention on One-Year Viral Suppression Among Pregnant Women Living With HIV and Their Male Partners in Malawi: A Randomized Controlled Trial

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Introduction: Couple-based behavioral interventions (CBIs) have been associated with improved HIV virological outcomes for pregnant women and their male partners living with HIV in observational settings, but have never been tested in a randomized controlled trial (RCT).

Setting: Bwaila District Hospital Antenatal Clinic (Lilongwe, Malawi).

Methods: An RCT was conducted among 500 pregnant women living with HIV (index clients) randomized 1:1 to the standard of care (SOC) or CBI and followed for 1 year. The CBI offered an initial session for index clients, HIV-assisted partner notification, 2 enhanced couple counseling and testing sessions, illustrated materials, and antiretroviral therapy pickup for either couple member at the antenatal clinic. At 12 months, viral load among index clients and male partners with HIV was measured. Risk differences (RD) and 95% confidence intervals (CIs) compared viral suppression (<1000 copies/mL) between arms.

Results: The mean index client age was 26.6 years; most were married or cohabiting (93.3%). Index client viral suppression was 6.5% higher in the CBI arm (88.0%) than in the SOC arm (81.6%). Male partner viral suppression was 16.2% higher in the CBI arm (73.6%) than the SOC arm (57.4%). Overall, couple viral suppression was 7.8% higher (CI: 0.5% to 15.1%, $P = 0.04$) in the CBI arm (84%) than in the SOC arm (76.0%). Social harms were rare (3.6%) and comparable between arms ($P = 0.8$).

Conclusions: This CBI had a positive impact on couple viral suppression. Scaling this CBI to antenatal clients with HIV and their male partners could improve HIV outcomes among expecting families.

Key Words: HIV, testing, couple, intervention, behavior, viral load, adherence

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INTRODUCTION

Women of reproductive age in Africa account for approximately one-third of the 37.7 million people living with HIV globally.[1] In most African countries, pregnant and breastfeeding women living with HIV are offered immediate lifelong antiretroviral therapy (ART) through Option B+, which has treatment benefits for women and prevention benefits for infants and partners.[2] Option B+ has increased ART initiation and retention in HIV treatment programs, including in Malawi.[3] However, the region has not eliminated vertical transmission, due to challenges with maternal viral

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suppression across the full perinatal period.[4,5] Furthermore, the male partners of pregnant women living with HIV experience lower levels of HIV testing and viral suppression than women.[6]

Engaging male partners in antenatal care (ANC) has benefits for women, partners, and infants.[7–9] One promising form of male engagement is couple HIV testing and counseling (CHTC), in which couple members learn their HIV status together from a counselor. CHTC has increased male partner HIV testing and disclosure, led to sexual behavior change, and improved infant outcomes, including HIV-free survival.[10–12] CHTC is often grounded in interdependence theory, the idea that behaviors can be influenced by the individual, partner, or the 2 together through dyadic processes, such as joint communication, decision-making, and goal setting.[13,14] CHTC is typically provided once, even though most couples require ongoing testing or support. Extending CHTC to support ongoing HIV-related behaviors, especially ART adherence, could have long-term HIV treatment benefits.

Although CHTC is often available in ANC settings,[15] it remains underused. One approach for increasing CHTC is through HIV-assisted partner notification, in which clinic staff help recruit sexual partners exposed to HIV.[16,17] When we pilot-tested HIV-assisted partner notification combined with CHTC, we observed increases in male partner HIV testing and ART initiation and female 1-month retention.[18] These couples described their strategies for mutual support with HIV-related behaviors.[19,20] Based on these observations, we developed a couple-based behavioral intervention (CBI) guided by interdependence theory, integrating HIV-assisted partner notification (to recruit couples) and CHTC (to test partners and support both couple members with ART behaviors).

In this analysis, we examine the impact of this CBI on viral suppression among pregnant women living with HIV (index clients), their male partners, and both together after 1 year. Secondarily, we examine male partner testing and social harms. We hypothesized that the CBI package would improve HIV-related outcomes compared with the standard of care (SOC).

METHODS

Study Setting

The study was conducted from September 2017 to August 2020 at Bwaila Hospital in Lilongwe, Malawi. This hospital attends to ~14,000 pregnant women annually; HIV prevalence is ~10%. Women without a documented HIV status are offered opt-out HIV testing at their first antenatal care (ANC) visit. Those with an HIV-positive result are encouraged to start the same-day ART.

Study Design

We conducted an unmasked 2-arm randomized controlled trial comparing Malawi's Option B+ SOC with a CBI. Five hundred pregnant women with an HIV-positive test result (index clients) were randomized (1:1) using permuted blocks of sizes 2, 4, and 6. The random allocation sequence was generated using SAS 9.4. Index clients were followed for 1 year with study visits at zero (enrollment), 6, and 12 months. Male partners of index clients randomized to the CBI arm could enroll at any point between the index client's 0-month and 12-month visits, with encouragement to enroll right away. Male partners in the SOC arm could only enroll at the index client's 12-month visit; delayed enrollment avoided study procedures influencing the outcome. In both arms, index client and male partner viral suppression were assessed at 12 months. Index client perception of (1) male partner HIV status and (2) male partner testing in the last year were also reported at 12 months.

Study Populations

Index clients who presented for antenatal care, tested HIV-positive, and were not already taking ART were eligible. Further eligibility characteristics included (1) being at the age of 18 years and older or at the age of 15–17 years and married, (2) expecting to remain in the Bwaila catchment area for the next year or notify the study of transfers, and (3) being in an ongoing heterosexual relationship for ≥3 months. The male partner was someone the index was (1) willing to invite to a couple-based intervention, (2) able and willing to provide locator information for, and (3) expected to be in the catchment area for ≥1 week in the next 6 months. In addition, index clients provided informed consent. Male partner consent was not required for index clients to enroll. Intimate partner violence (IPV) was discussed as a potential risk. Women who believed participation would lead to IPV were discouraged from consenting.

Male partners were eligible if they (1) were aged 18 years and older or 15–17 years and married, (2) in a relationship with the index client for ≥3 months, and (3) willing to receive CHTC with the index client. Male partners provided informed consent. Only 1 partner could be enrolled per index client, but new partners could enroll if the first relationship ended.

Study Procedures

Pregnant women with routine HIV-positive test results first provided verbal consent for eligibility screening. Eligible women who wished to participate then provided written informed consent. A research officer administered a tablet-based behavioral survey using Open Data Kit, assessing demographic and relationship characteristics, sexual and reproductive health, and IPV. Next, locator information was collected. Finally, a research officer opened a sealed envelope and provided randomization assignment. At 6 and 12 months, the behavioral survey was repeated and index clients were asked to report social harms (ie, challenges arising from study participation). At the 12-month visit, a plasma sample was collected for measurement of HIV viral load with GeneExpert (lower detection limit = 40 copies/μL). For index clients randomized to CBI, intervention procedures were then conducted.

Although enrollment timing differed for male partners in the SOC (12 months) and CBI arms (0–12 months), enrollment procedures were the same: verbal consent for screening, eligibility screening, and administration of informed consent. Men in the CBI arm completed the behavioral survey at 0 (0–<4), 6 (4–<10), and 12[10–14] months after index client enrollment. They received intervention procedures at each visit. Men in the SOC arm completed the survey and were offered intervention procedures at 12 months. At the 12-month visit, men in both arms provided a venous blood sample to determine HIV status and viral load.

Index clients and male partners who failed to present to the clinic for their 12-month visit were traced and offered community-based procedures analogous to clinic-based procedures except 70-μL dried blood spots were collected in lieu of phlebotomy. HIV RNA PCR testing was conducted on Abbott HIV Viral Load Real-Time testing with a lower detection limit of 1000 copies/μL. This value was used as the lower limit for all samples.

At all study visits, social harms related to study participation were assessed, as well as the nature of harm (physical, emotional, economic, social, and legal) and the people involved. Study staff provided support and referrals.

SOC and CBI

Index participants received routine Option B+ procedures from facility staff (Table 1). They received TDF/3TC/EFV starting in October 2017, had the option to switch to TDF/3TC/DTG in June 2019, and were expected to switch in February 2020. At the first antenatal visit, all pregnant women were tested for HIV using group pretest counseling, serial HIV rapid testing, and individual posttest counseling. Women could bring a sexual partner, but most did not. Referral slips were inconsistently offered to women who presented without a partner. Male partners who were HIV-positive could not obtain ART at the ANC facility; they were referred to an HIV clinic <100 meters away.

Those assigned to the CBI arm received an intervention called *Timasamalirana,* a Chichewa phrase meaning "we support each other." *Timasamalirana* was based on formative research exploring how HIV-affected couples supported each other with ART behaviors. We incorporated these findings into an enhanced CHTC intervention focused on ART adherence. *Timasamalirana* was grounded in interdependence theory, focusing on dyadic processes, such as intracouple communication (discussing HIV-related behaviors), joint decision-making (making decisions together about HIV-related behaviors), joint goal-setting (setting behavioral goals together), and communal coping (supporting each other with the emotions arising from an HIV diagnosis). It comprised an index client initial visit, in which women were offered support on disclosing to and inviting partners, assisted partner notification, enhanced CHTC, illustrated pamphlet reinforcing key messages, and opportunity for both couple members to obtain ART at ANC. Counselors and nurses with prior CTHC training delivered *Timasamalirana*, using checklists to guide delivery.

- *Index client initial visit (day 0–7):* This individual session focused on coping with the diagnosis and disclosing to and inviting a male partner. Index clients received an illustrated

TABLE 1. Comparison of CBI and SOC Procedures

	CBI	SOC
Initial visit (day 0–7)		
HIV testing during antenatal care (individual or couple testing available)	✓	✓
Distribution of family referral slip to invite male partner for testing	✓	✓
Counseling on disclosure and partner recruitment	✓	
Partner invitation for pregnancy information	✓	
Partner recruitment (first 3 months)		
Phone and physical tracing if couple does not present	✓	
Couple visit 1 (first 3 months)		
Enhanced couple counseling and testing	✓	
Joint goal-setting, problem-solving, couple communication around treatment, prevention, and PMTCT behaviors		
Male partner ART initiation in ANC setting	✓	
Illustrated materials reinforcing pregnancy and HIV messages	✓	
Couple visit 2 (6 months)		
Enhanced couple counseling and testing	✓	
Joint goal-setting, problem-solving, couple communication around treatment, prevention, and PMTCT behaviors		
Ongoing		
Either couple member could pick up pills for partner or themselves	✓	
Final couple visit (12 months)		
Phone and physical tracing	✓	✓
Enhanced couple counseling and testing	✓	✓
Joint goal-setting, problem-solving, couple communication around treatment, prevention, and PMTCT behaviors		
Illustrated materials reinforcing HIV messages	✓	✓

invitation encouraging a partner to come to the clinic to receive pregnancy-related health information within 1 month. Procedures for phone and physical tracing were offered if their partners did not present.

- *Male partner tracing procedures (month 1–3):* For partners who did not present after 1 month, phone and physical tracing began and continued for 2 months. The tracer followed a script reinforcing invitation messages and omitting the index client's HIV status.
- *Couple visit 1 (first 3 months):* Couples were provided with pregnancy information, including the importance of CHTC, and offered enhanced CHTC with differentiated messages based on couple status. Messages focused on retention and ART adherence. Consistent with interdependence theory, the counselor promoted intracouple communication and encouraged joint decision-making and joint goal-setting. Men who tested HIV-positive could initiate ART in the antenatal clinic.
- *Subsequent couple visits (month 6, 12)*: Couples received up to 2 follow-up sessions. Repeat testing was conducted for male partners in HIV-discordant couples. Messages on retention and ART adherence were reinforced. Intracouple communication, joint decision-making, and joint goal setting were revisited.
- *Ongoing procedures*: Couple members could pick up HIV treatment for themselves or one another at the ANC.

Outcomes

The primary outcome was the proportion of index clients who were HIV virally suppressed (<1000 copies/μL) at 12 months. The study had 83% power to detect a 10% difference in the proportion of index clients virally suppressed between arms. Among male partners living with HIV, viral suppression was the primary outcome. The study had 90% power to detect a 20% difference in the proportion of male partners virally suppressed. Viral suppression was also examined in a combined analysis among all index clients and male partners living with HIV. Secondary outcomes included partner HIV status, index client report of partner HIV status, and index client report of partner testing in the last year. Female report was used because partner testing could have occurred outside of our study; thus, our observation of male partner testing was incomplete. However, male self-report of HIV testing is also provided. We also examined the number and nature of social harms.

Analysis

Index client viral suppression was analyzed using complete case and multiple imputation (MI) approaches. Complete case analysis was restricted to index clients with a 12-month viral load outcome. In the MI analysis, viral load outcomes were imputed using fully conditional specification with 50 imputed data sets. Each imputation model included our exposure and variables associated with viral suppression and study participation, such as visit attendance. Rubin[21] rule was used to combine results. Complete case analyses were used for all other outcomes.

For each individual-level primary and secondary outcome, a generalized linear model with an identity link and binomial distribution was used to estimate risk differences (RD) between arms and 95% confidence intervals (CI). For combined viral suppression among index clients and male partners living with HIV, a generalized estimating equation (GEE) with an identity link and binomial distribution was implemented to account for intracouple correlation. This model included an exchangeable correlation matrix and robust variance estimators. To compare social harms, a Fisher exact test was used.

In planned secondary analyses, we examined whether intervention dose was associated with viral suppression among index clients. We also evaluated whether the relationship between the intervention and index client viral suppression was modified by key relationship characteristics, including self-report of recent IPV at baseline. IPV was of interest, as many couple-based programs exclude such individuals. We used the revised Conflict Tactics Scale to measure IPV in the month before study enrollment and generated dichotomous variables for physical, sexual, and emotional violence.[22]

Ethics

This protocol was approved by Malawi National Health Sciences Research Committee (17/03/1747) and the University of North Carolina at Chapel Hill Institutional Review Board (17–0681) and registered at clinicaltrials.gov (NCT 03477279).

RESULTS

Study Populations

Most women screened were eligible (85.6%) (Fig. 1). Primary reasons for ineligibility were not having a sexual partner at all (21.2%) or in Lilongwe (39.4%), and not being able or willing to provide partner locator information (24.8%). Among eligible women, 10.7% did not provide informed consent and 27.7% were unavailable (ie, did not wish to remain at the clinic to complete study procedures right after their HIV diagnosis). Overall, 500 index clients were consented, enrolled, and randomized.

The mean age of index clients was 26.5 years (SD = 5.4) (Table 2). Most index clients (71%) enrolled in their second trimester; 20% were primigravida. Most (90%) had been tested for HIV, although few (8%) had received an HIV-positive test result. Nearly all index clients reported being married or cohabitating with their partner (93%); the median relationship length was 2.1 years (interquartile range: 1–6 years). Some women reported emotional (18%), physical (7%), or sexual (11%) IPV in the last month with their expected study partner. Only 16% of index clients presented to their initial ANC visited with a partner.

Overall, 72.6% of index clients completed a 6-month visit and 81.0% completed a 12-month visit. Retention was similar between CBI and SOC at 6 (73.2% vs. 72.0%, P =

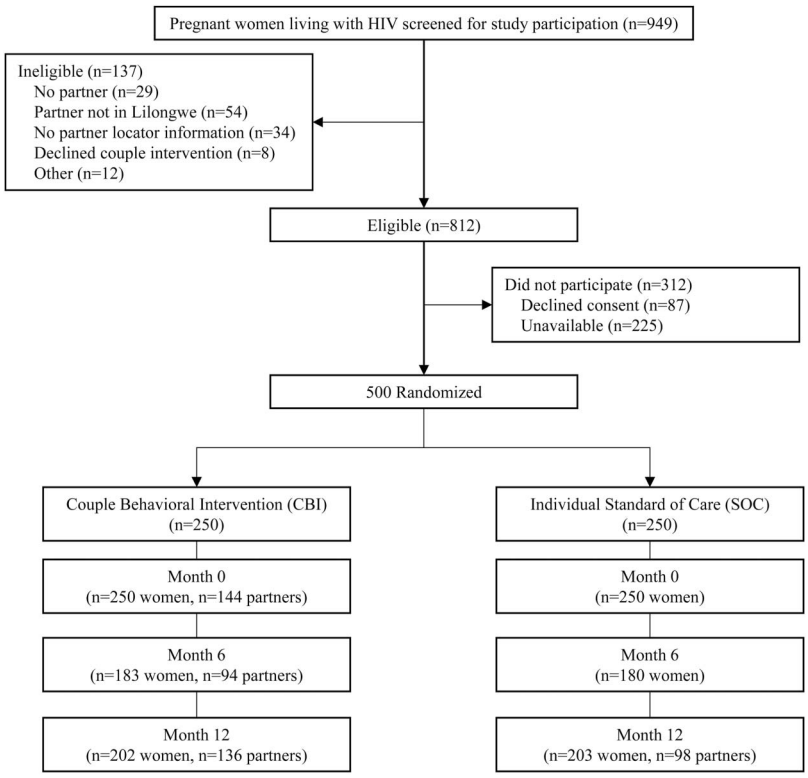

FIGURE 1. Consort diagram. This figure displays the consort diagram for the *Timasamalirana* trial.

0.8) and 12 months (80.8% vs. 81.2%, $P = 0.9$) (Appendix 1). Younger and primigravida women were less likely to have a 12-month visit.

About half of index clients (n = 264, 52.8%) had a male partner who consented and enrolled. Male partner participation differed by arm (CBI: 166/250; SOC: 98/250). The mean partner age was 33.2 years (SD = 7.0). Two women in the CBI arm had 2 partners enroll over the course of 12 months. Of 236 partners who never presented, 53.8% were not locatable, 28.0% had relationships that ended, 16.1% were not interested, and 2.2% died. Challenges locating partners were due to difficulties finding addresses, address changes, and absences at the time of tracing.

CBI Engagement

In the CBI arm, 143 couples (57.2%) had an initial couple visit (0–4 months) and 92 (36.8%) had a 6-month visit (5–8 months). Ninety-nine CBI couples (39.6%) did not have any couple visits, 70 couples (28.0%) had 1 visit, and 81 (32.4%) had 2 visits. Couples' first visit involved both partners testing (24%), only the male partner testing (44%), and neither partner testing (31%). All included counseling.

Viral Suppression Outcomes

In complete case analysis, there was a trend toward higher 12-month index client viral suppression in the CBI arm (88.0% vs. 81.6%; RD: 6.5%, CI: −0.9% to 13.8%, $P = 0.08$). Risk differences were similar in MI analysis, although point estimates were lower (81.1% vs. 74.2; RD: 6.9%, CI: −1.8% to 15.6). Women in the CBI arm who received 2 couple counseling sessions (n = 81) were more likely to be virally suppressed than women in the SOC arm (91.4% vs. 81.6%; RD: 9.8%, CI: 1.4% to 18.1%, $P = 0.02$). Adherence levels were 86.8% and 84.0% for those with zero and 1 session, respectively.

Imprecise trends were suggestive of effect measure modification by relationship characteristics. The CBI had a positive effect among those who did *not* experience recent physical IPV (RD: 7.9%, 95% CI: 0.2% to 15.5%), but not among those with recent physical IPV (RD: −9.6%, −41.6% to 22.3%; Fig. 2). The CBI also had a positive effect among women who reported being married or cohabitating and those in a relationship for at least 1 year.

More partners had a 12-month visit in the CBI arm than the SOC arm (54.4% vs 39.2%, $P < 0.01$). Among men who presented at 12 months, nearly all (98.3%) were tested for HIV. The proportion of men who tested HIV-positive was comparable between arms (52.9% vs. 55.1%, $P = 0.7$). Among men living with HIV, viral suppression was more common in the CBI arm (73.6% vs. 57.4%; RD: 16.2%, CI: −0.5% to 32.9%, $P = 0.06$).

Examining index clients and male partners together, viral suppression was more common in the CBI arm (84.0% vs. 76.0%, RD: 7.8%, CI: 0.5% to 15.1%, $P = 0.04$).

Secondary Outcomes

At 12 months, women in the CBI arm were more likely to report knowing their partner's HIV status (82.2% vs. 71.8%; RD: 10.3%, CI: 1.8% to 18.9%, $P = 0.02$) and that

TABLE 2. Baseline Characteristics of Female Participants

	CBI (n = 250)	SOC (n = 250)
Age, yrs (%)		
<20	24 (10)	27 (11)
20–24	73 (29)	77 (31)
25–29	75 (30)	71 (29)
≥30	77 (31)	71 (29)
Educational attainment (%)		
Did not complete primary school	109 (44)	100 (41)
Primary school complete	108 (43)	106 (43)
Secondary school complete	32 (13)	40 (16)
Estimated gestational age, mo (%)		
1–3	29 (13)	25 (12)
4–6	155 (70)	156 (72)
≥ 7	39 (17)	35 (16)
Number of past pregnancies (%)		
0 prior pregnancies	50 (20)	48 (20)
1 prior pregnancy	49 (20)	66 (27)
≥2 prior pregnancies	150 (60)	132 (54)
Most recent HIV test result (%)		
Never tested	23 (9)	28 (11)
HIV negative	202 (81)	195 (80)
HIV positive	21 (8)	19 (8)
HIV indeterminate	3 (1)	3 (1)
Partners in last 6 mo (%)		
0 sex partners	2 (1)	0 (0)
1 sex partner	233 (94)	238 (97)
≥2 sex partners	13 (5)	7 (3)
Marital status (%)		
Not married or cohabitating	14 (6)	19 (8)
Married or cohabitating	235 (94)	227 (92)
Length of relationship, yr		
<1	49 (20)	53 (22)
1–4	112 (45)	125 (51)
5–9	48 (19)	34 (14)
≥10	39 (16)	33 (13)
Partner age difference (%)		
Male partner < 5 years older	80 (36)	93 (43)
Male partner 5–9 years older	66 (30)	62 (29)
Male partner ≥ 10 years older	36 (16)	33 (15)
Does not know partner age	40 (18)	29 (13)
Primary partner HIV status (%)		
HIV negative	117 (47)	100 (41)
HIV positive	28 (11)	25 (10)
HIV indeterminate	2 (1)	0 (0)
HIV status unknown	102 (41)	121 (49)
Past couple testing (%)		
Yes	79 (32)	68 (28)
No	168 (68)	177 (72)
Emotional IPV in past 30 d (%)		
Yes	46 (18)	45 (18)
No	203 (82)	201 (82)
Physical IPV in past 30 d		
Yes	13 (5)	23 (9)
No	236 (95)	223 (91)
Sexual IPV in past 30 d (%)		
Yes	28 (11)	28 (11)
No	221 (89)	218 (89)

Column totals may not sum to 250 due to missing data.

their partner had HIV testing in the last year (72.2% vs. 57.1%; RD: 15.1%, CI: 4.7% to 25.5%, $P = 0.05$; Table 3).

Social Harms

Eighteen social harms were reported with similar frequency across arms ($P = 0.8$). Most (78%) involved family or people in the home (typically the partner); the rest involved friends. Most were emotional (83%) or financial (28%); 2 were physical (11%). One woman in the CBI arm was assaulted by her partner because he was angered by study participation. She was referred for medical and psychosocial support and elected to remain in the study.

DISCUSSION

Our trial evaluated the impact of a CBI on viral suppression among pregnant women living with HIV and their male partners 1 year after HIV testing. The CBI improved viral suppression at 12 months when both partners were considered together. When men and women were considered separately, improvements in viral suppression were observed, although not statistically significant.

Within ANC, couple-based interventions improve male partner HIV testing, vertical transmission, maternal ART initiation, and condom use, but the impact on female and male partner viral suppression had not been assessed previously.[9,10,23,24] Male engagement, such as HIV status disclosure, clinic attendance, and coenrollment in care, is associated with maternal retention, treatment adherence, and viral suppression in observational studies.[25–30]

Our study is the first randomized assessment of a couple-based intervention on viral suppression in an African setting. It is also one of the first to show an impact on maternal or male partner cascade outcomes.[31–33] One key study examined Mozambican pregnant women living with HIV and their male partners. An intensive multisession CBI had no effect on ART refills for women and only a small effect on ART refills for men.[33] Our stronger effects are likely due to a different comparison group. Our comparison group was a cohort of individual women, whereas the Mozambican comparison group was a cohort of couples who were aware of each other's status. This suggests that the simple act of bringing couples together may be more impactful than ongoing counseling.

Timasamalirana integrates HIV-assisted partner notification with enhanced CHTC. In traditional HIV-assisted partner notification, partners are contacted anonymously, a practice that protects the identity of the index but often misses benefits for couples. Drawing on interdependence theory, we engaged partners as collaborators who could provide and benefit from the index client's support.[20,34] Facilitating couple engagement, interdependence, and couple communication stands in contrast to many partner notification interventions, which offer counseling to couple members separately.[28] Our formative work, which unearthed existing forms of support,[19] was integrated into *Timasamalirana*. Interdependence theory has been incorporated into similar ongoing trials in SSA, with results

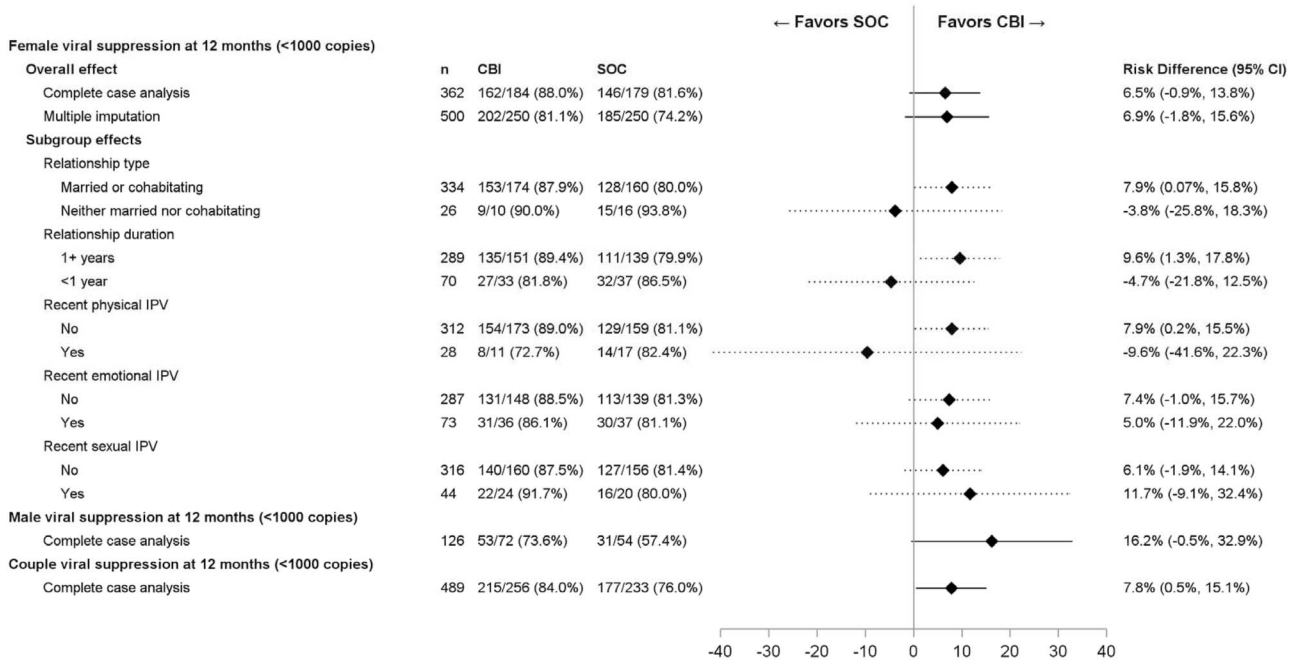

FIGURE 2. Index client, partner, and couple viral suppression at 12 months. This figure compares viral suppression for the CBI and SOC.

forthcoming[35,36] and impactful studies in the United States.[37]

Couple-based behavioral interventions are appropriate for many, but not all pregnant women with HIV. We excluded women who did not wish to engage in a couple-based intervention, did not have a partner, or did not believe their partner would be available. Some eligible women declined to provide consent due to the nature of the intervention. Together, these groups represented approximately 1 quarter of the women that we screened. In addition, some women did not have time or interest to participate in a study on the day of their HIV diagnosis. Furthermore, women in the CBI arm who were in shorter, nonmarital relationships and violent partnerships did not exhibit higher levels of viral suppression. These findings are comparable with a South African study which found HIV status disclosure associated with viral suppression only among women in married/cohabiting relationships.[25] Based on the lack of effectiveness and the potential for harm, restricting couple-based interventions to couples without recent physical intimate partner violence is advised and the current standard in Malawi index case testing program. Different interventions, or a different type of supporter, may help women experiencing IPV, a population in need of support.[38]

Timasamalirana is 1 type of treatment-supporter intervention, a program that leverages social support to achieve HIV outcomes. Treatment supporters, especially those selected by the patient, also positively affect viral suppression in similar settings.[39–41] Such interventions are promising as they require minimal resources and often offer daily support. Although adults on ART in Malawi identify a treatment supporter, their role is often limited to medication pickup. Our

TABLE 3. Male Partner Outcomes at 12 Months

	CBI		SOC				
	n/N	(%)	n/N	(%)	RD	(95% CI)	*P*
Male outcomes							
Female aware of primary partner HIV status at 12 mo	152/185	(82.2%)	130/181	(71.8%)	10.3%	(1.8% to 18·9%)	0.02
Female report of primary partner HIV testing in past 12 mo	117/162	(72.2%)	88/154	(57.1%)	15.1%	(4.7% to 25·5%)	<0.01
Male report of HIV testing in the past 12 mo	82/102	(80.4%)	47/69	(68.1%)	12.3%		0.07
Male outcomes (ascertained from male partner's blood sample)							
Male partner HIV status							
HIV positive	72	(28.8%)	54	(21.6%)			
HIV negative	63	(25.2%)	41	(16.4%)			
Refused testing	1	(0.4%)	3	(1.2%)			
Not observed	114	(45.6%)	152	(60.8%)			

intervention substantially expanded the nature, interactivity, and scope of this role.

Our intervention holds promise for scale-up, given its impact on multiple outcomes of interest to UNAIDS and national HIV programs. Our intervention required only 1 individual counseling session, assisted partner notification, and 2 CHTC sessions that could be aligned with other antenatal and infant milestones. Furthermore, individual components are already part of many national programs.

Study procedures were intentionally minimal. Index client study visits were spaced 6 months apart to prevent study retention from influencing clinical retention. One consequence of this decision was index client loss to follow-up, a limitation. To address this limitation, we observed retention was similar between arms; in addition, MI and complete case findings were similar, suggesting the results were not driven by differential follow-up.

Male participation in the intervention and trial were lower than expected, another set of limitations.[6,28] Only 60% of men participated in the counseling sessions. Nonetheless, the intervention improved male partner HIV testing from a baseline of 16%. Suboptimal participation was due, in part, to contextual factors, including long-distance relationships, challenges finding physical locations, and relationship dissolution. As a result, power to detect a difference in viral suppression was reduced. Despite moderate participation, we observed a difference in viral suppression between arms, suggesting resilience to imperfect implementation.

We do not report on vertical HIV transmission due to difficulties linking maternal and infant records or on sexual transmission due to the relatively small sample size. These omissions are another limitation. However, viral suppression is known to reduce both vertical and sexual transmission, and we would expect these downstream benefits.[42,43]

Despite a decade of Option B+ scale-up, most African countries have not eliminated HIV vertical transmission nor achieved adult 95-95-95 UNAIDS targets. *Timasamalirana,* a simple and scalable intervention, could affect both sets of targets if brought to scale.

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