Results of a couples-based randomized controlled trial aimed to increase testing for HIV

Running head: Couples-based RCT to increase CHTC

Lynae A. DARBES, Ph.D., Nuala M. MCGRATH, Ph.D., Victoria HOSEGOOD, Ph.D., Mallory O. JOHNSON, Ph.D., Katherine FRITZ, Ph.D., Thulani NGUBANE, MTH, Heidi VAN ROOYEN, Ph.D.

Word count: 3500

Portions of these results were presented by Lynae Darbes at the XXIst International AIDS Conference, Durban, South Africa, July 20th, 2016.

Center for AIDS Prevention Studies, University of California, San Francisco, San Francisco, CA, USA (Lynae A. Darbes, Ph.D.)*;
Division of Primary Care and Population Sciences, Faculty of Medicine, and Department of Social Statistics and Demography, Faculty of Social Sciences, University of Southampton, Southampton, UK (Nuala M. McGrath, Sc..D., Professor); Department of Social Statistics and Demography, Faculty of Social Sciences , University of Southampton, Southampton, UK (Victoria Hosegood, Ph.D., Professor); Center for AIDS Prevention Studies, University of California, San Francisco, San Francisco, CA, USA (Mallory O. Johnson, Ph.D., Professor), International Center for Research on Women, Washington, D.C., USA (Katherine Fritz, Ph.D.) Human Sciences Research Council, Durban, South Africa, (Thulani Ngubane, MTH); Human Social Development, Human Sciences Research Council, Durban, South Africa (Heidi van Rooyen, Ph.D.) *LAD is currently at the Department for Health Behavior and Biological

Sciences, Center for Sexuality and Health Disparities, University of Michigan School of Nursing, Ann

Arbor, MI, USA

Correspondence and request for reprints to Dr. Lynae A. Darbes, Department of Health Behavior and

Biological Sciences, Center for Sexuality and Health Disparities, University of Michigan School of

Nursing, 400 N. Ingalls, RM 3341, Ann Arbor, MI 48109, USA

ABSTRACT

Background

Although couples-based HIV testing and counseling (CHTC) is effective for facilitating mutual disclosure and linkage to HIV care, uptake remains low. Using a randomized controlled design, we tested the efficacy of a behavioral couples-based intervention aimed to increase CHTC.

Setting:

The Vulindlela district of KwaZulu-Natal, South Africa.

Methods

Couples were recruited from the community (e.g., markets, community events). Couples were excluded if mutual HIV serostatus disclosure had occurred. Both partners had to report being each other's primary partner and relationship length was at least six months.   Assessments occurred at baseline, and 3-, 6-, and 9-months post-intervention.

Eligible couples attended a group session (3-4 hours) after which randomization occurred. Intervention couples additionally received: one couples-based group session followed by four couples' counseling sessions (1-2 hours). Intervention topics included communication skills, intimate partner violence, and HIV prevention. Our primary outcomes were CHTC and sexual risk behaviour.

Results

Overall, 334 couples were enrolled. Intervention couples were significantly more likely to have participated in CHTC (42% v. 12% [p ≤ 0.001]). Additionally, their time to participate in CHTC was significantly shorter (logrank p ≤ 0.0001) (N=332 couples). By group, 59% of those who tested HIV-positive in intervention and 40% of those who tested in control were new HIV diagnoses (p = 0.18). There were no group differences in unprotected sex.

Conclusion

Our intervention improved CHTC uptake—a vehicle for mutual serostatus disclosure and entrée into HIV treatment, both of which exert a significant public health impact on communities substantially burdened by HIV.

Keywords: HIV testing, couples, RCT, CHTC, South Africa

INTRODUCTION

South Africa is one of the countries most impacted by HIV, with a generalized epidemic and an HIV prevalence of 17.9% among 15-49-year olds [1]. In KwaZulu-Natal province, recent estimates indicate an HIV prevalence of 39.5% among women seeking antenatal care[2]. Improved and earlier access to HIV treatment are facilitating a reduced HIV burden[3], but complicating issues hinder progress in this context[4]. These include low HIV testing rates, especially for men[5], and low rates of HIV serostatus disclosure[6]. Most HIV infections in sub-Saharan Africa occur among heterosexual primary partnerships[7]. Therefore, couples-based approaches have been recommended as a way to leverage partner influence[8]. However, factors such as low marriage rates and infrequent cohabitation [9] (a result of employment-related migration) render unique challenges for couples-based approaches.

Efforts to increase HIV testing have paid less attention to innovative strategies that may combat barriers to uptake. Among a myriad of challenges (e.g., low HIV testing, disclosure), couples HIV counseling and testing (CHTC) has been recommended by the WHO given its several benefits, including: 1) being an entrée into ART initiation, 2) a springboard for primary and secondary HIV prevention efforts, 3) an opportunity for adoption of safer conception strategies, and, 4) a means of strengthening and enhancing positive relationship dynamics and support between partners[10]. CHTC entails simultaneous HIV testing for partners and facilitated mutual disclosure. Previous research has found that CHTC promotes sexual risk reduction, especially among serodiscordant partnerships[11-13]. However, despite its benefits, uptake of CHTC has remained low across multiple contexts in Sub-Saharan Africa (SSA) and specifically in South Africa.

While CHTC itself addresses aspects of relationships such as communication, few couples-based interventions in SSA have focused on the role of other relationship dynamics such as satisfaction, intimacy, or gender-based power. The direction of influence of these dynamics on behaviors such as sexual risk behavior, HIV serostatus disclosure, and HIV testing has been inconsistent[14-16]. However,

couples-based studies in SSA have illustrated the importance of relationship dynamics, including trust

and commitment[17], and identified the crucial role that partners can play in the context of HIV. Therefore,

there is a need for interventions that target couples, increase uptake of CHTC, and examine the role of

relationship dynamics on HIV testing and sexual risk behavior. Thus, the aim of our study was to test the

efficacy of a behavioral couples-based RCT to increase CHTC in an area of high HIV prevalence. Based

on our prior work and that of others, we also investigated whether the intervention would reduce sexual

risk behavior [14-15]. Our hypothesis was that the intervention would lead to increases in CHTC and declines

in sexual risk behavior.

METHODS

Study Design

Our intervention, Uthando Lwethu ("Our Love" in isiZulu), was evaluated through an RCT

(Figure 1), conducted in rural KwaZulu-Natal, South Africa.

The intervention was conducted with the understanding and consent of each participant. Ethical

approval was obtained through the Committee on Human Research of the University of California, San

Francisco, the Research Ethics Committee of the Human Sciences Research Council in South Africa, and

London School of Hygiene and Tropical Medicine, UK. The study protocol is available at:

htttp://www.clinicaltrials.gov. Additional details on procedures and intervention have been published

previously[18].

Participants

Inclusion criteria specified couples aged between 18-50, whose relationship was at least 6

months, were not in a polygamous marriage, and both partners indicated each other as their primary

partner to whom they were committed and with whom they had sexual relations. Given our primary

outcome of CHTC, couples were ineligible if they had previously tested together for HIV. Couples were

ineligible if both partners had mutually disclosed their HIV status, as they likely had sufficient relationship and/or communication skills to achieve our study objective (mutual disclosure via CHTC). The intervention was not appropriate for couples experiencing current intimate partner violence (IPV), but we did not exclude couples for past history of IPV, as this would limit generalizability. Rather, we excluded and provided referrals for couples reporting current or recent severe violence (physical or sexual violence in prior 6 months).

Procedures

Recruitment.

Participants were recruited between March 16 2012 and August 24 2014 by trained recruiters using active and passive strategies. Active strategies included approaching couples in public areas such as markets, taxi ranks, and community events. Recruiters worked in male-female teams, as we found in prior research that couples respond well to mixed-gender teams[18]. Passive strategies included posting flyers. All recruitment activities were conducted using a mobile caravan with two private rooms, in which partners could be interviewed separately. The caravans allowed us to reach a wide geographic catchment area, and were used for recruitment, screening, conducting baseline and follow-up surveys, and delivering intervention sessions.

After providing verbal consent, each partner completed a short initial screening, assessing key eligibility criteria (relationship length, age, sexually active, polygamous marriage). This could be conducted by phone or in-person. If both partners (screened separately) were eligible, then a secondary screening occurred, which included written informed consent, either immediately after initial screening, or at a later time. The secondary screening determined final eligibility, including history of IPV and mutual HIV serostatus disclosure. Following completion of secondary screening, eligible couples were invited to enroll, and after completing informed consent, they were asked to complete a baseline survey.

Couples who remained eligible after the baseline survey were invited to attend the next scheduled first group session, with a target of 20 couples per session.

Randomization

Couples were randomized at the completion of the first group session. The control condition only received the first group session and participated in subsequent follow-up assessments. Intervention couples received an additional group session and four couples counseling sessions. Randomization was conducted at the couple level, using permuted-block randomization of three different block sizes, 8, 10, and 12, in order to blind staff as well as participants to the next assignment. Allocation concealment was achieved by opaque envelopes.

The random sequence was generated by the study statistician (N.M.), who prepared the envelopes in their entirety at the beginning of the study. Randomization was conducted by the Project Director (T.N.) with assistance from study staff.

Due to the nature of the intervention, masking was not possible. Therefore, neither the staff nor participants were unaware of group assignment. However, assessment interviewers were separate staff from couples' counselors and group facilitators.

Intervention activities

The full intervention comprised 5 sessions (one group and four couples' counseling sessions.) All couples participated in the first group session. This was four hours, and co-led by a pair of male-female facilitators. Content covered information on health topics, including alcohol use, sexually transmitted infections (STIs), HIV/AIDS (including HIV testing and CHTC), and reproductive health. The format was interactive, and materials covering local resources and referrals were provided. Occurring one week later, Session 2 was delivered to intervention couples in single-gender groups contemporaneously. This was a smaller group of 6-10 couples, led by a gender-matched facilitator and lasted approximately four

hours. Topics covered included relationship dynamics and their influence on risk for HIV, IPV, and gender-based power. Communication skills were provided in the form of the "Speaker-Listener technique", adapted from the PREP couples relationship program and validated previously in a black South African population [15,19]. Sessions 3-6 were two-hour couples' counseling sessions, provided by one counselor to individual couples. These sessions were delivered in the study caravan to ensure privacy. The four sessions follow a sequence in which the goals of the intervention were discussed, and the couples identified a specific HIV-related goal to focus on in their sessions. A standardized set of exercises and skills were provided, aimed to improve the couples' ability to problem-solve, improve communication, and enhance their relationship. At the final session, the counselor reviewed the couples' progress in meeting goals, discussed any potentially challenging upcoming events, reviewed strategies to cope with them and discussed community resources and support from their families and friends. Couples assigned to the control condition were eligible to participate in a condensed form of the couples counseling sessions following the completion of their participation (9-month follow-up).

All couples (intervention and control) were informed of the benefits of CHTC, and all couples received monthly text reminders to participate in CHTC and the location of the mobile study caravan which provided CHTC.

Assessments

Follow-up assessments were done at 3-, 6-, and 9-month post-randomization. The surveys contained several standardized scales assessing relationship functioning, sexual behavior, and demographic information, and mirrored the information collected at baseline. The survey was administered via a face-to-face interview with a gender-matched interviewer utilizing mobile-phone software Mobenzi Researcher™ (Durban, South Africa). The survey took approximately 45 minutes -1 hour to complete. Couples completed their surveys separately but simultaneously.

Our primary outcomes were participation in CHTC and sexual risk behavior. This was determined by the couple participating in CHTC with our study staff (a testing counselor separate from assessment and intervention staff). Each episode of CHTC was documented by study records, including the results of each partners' HIV test. We hypothesized that the proportion of participants who participated in CHTC by 9-month follow-up would be higher in the intervention group than in the control group. We also hypothesized that the time to participation in CHTC would be shorter in the intervention group relative to the control group. For sexual risk behavior, we hypothesized that intervention participants would report fewer acts of unprotected sexual intercourse with primary sex partners relative to the control group.

Statistical Analysis

For primary analysis examining whether the intervention was successful in terms of couples participating in CHTC by the final follow-up assessment, our initial power analysis assumed 700 participants/350 couples at baseline. However, this recruitment target assumed an attrition rate of 20% due to break-ups and 10% due to other causes, anticipating a final proposed sample size of 490 individuals/245 couples still in follow-up at 9 months. We computed the minimal detectable odds ratio on an assumption of low prevalence of CHTC (10%) and a medium prevalence of CHTC (30%). For these scenarios, the resulting standardized effect size metrics were between a small ($h = 0.20$) and medium ($h = 0.50$) standardized effect size.

The analyses followed an intent-to-treat approach. First, we compared the proportion of couples that had participated in CHTC by 9 months between the two arms. A log rank test was used for a time-to-event analysis across the two groups. For the outcome of unprotected sex acts with the enrolled partner in the last 3 months, a negative binomial regression model accounting for couple clustering was used, with an offset for the number of sex acts with partner in the last three months. We originally intended to examine numbers of outside sexual partners as an outcome, however too few occurrences of this outcome

precluded this analysis (at baseline 5% of men and 0.2% of women reported any outside sexual partners in the previous three months).

Stata v13 was used for all analyses.

The study was overseen by a Data Safety and Monitoring Board made up of behavioral scientists and a statistician from the US and South Africa. The trial was registered in the US via the clinicaltrials.gov website (http://www.clinicaltrials.gov) (NCT01953133).

RESULTS

Following screening 1202 individuals there were 534 individuals who were either excluded (n = 264) or did not participate although they were eligible at screening or baseline (n=270). Most exclusions were due to already participating in CHTC (33%) or to insufficient length of partnership (22%). We randomized 334 couples (168 couples to intervention, 166 to control). Two couples retrospectively were found to have already mutually disclosed and thus were ineligible for the study. During follow-up, 6 couples broke up and 16 couples were lost to follow-up, although our attrition was much lower than assumed for sample size calculations. Retention across groups at 9-month follow-up was 93%. Please see Figure 1 for the trial profile with additional details. Baseline characteristics of the sample are included in Table 1. We checked that characteristics were balanced across the two groups at baseline. At the couple level, all characteristics were balanced. At the individual level, individuals in the control group were more likely to be married (23% vs 20%) and slightly older (median 27 vs 26 years) than individuals in the intervention arm.

Completion rate for the intervention sessions was 83% for all four sessions, and 92% of couples attended partial intervention sessions (1-3 sessions) (Figure 1).

Intent-to-treat analysis included 332 couples, and showed that intervention couples were more likely to participate in CHTC than control couples (42% v. 12% [p $\leq$ 0.0001]). There was also a significantly shorter time to participate in CHTC for intervention couples (logrank p $\leq$ 0.0001) (Figure 2).

Of the intervention couples that participated in CHTC, 46% were concordant HIV-negative, 30% were concordant HIV-positive, and 24% were serodiscordant. The female partner was HIV-positive in 12/17 discordant couples. For control couples, 55% were concordant HIV-negative, 30% were concordant HIV-positive, and 15% were serodiscordant. The female partner was HIV-positive in one of three discordant couples. By group, 59% of those who tested HIV-positive in intervention arm and 40% of those who tested in control arm were new HIV diagnoses (p $=$ 0.18) (Table 2).

For unprotected sex, the group-by-time interaction was not significant in the model overall (p=.08), but there was a significant reduction in unprotected sex with primary partners for intervention couples at 3-month follow-up (IRR = 0.74, p $\leq$ 0.022).

There was one adverse event during the course of the trial; a couple broke up and the male partner attributed their break-up to participation in the trial although the female partner did not.

Discussion

Our study demonstrated the efficacy of a relationship-focused, couples-based intervention on participation in CTHC as compared to control. Our hypotheses were supported in that the intervention successfully promoted CHTC, as well as a rapid uptake of this service. At baseline, almost 40% of the participants had never tested for HIV -- in an area of high HIV prevalence. In addition, the vast majority of participating couples had not disclosed the results of any prior HIV test to their study partner at baseline. Both findings indicate that the study reached a population in need of intervention. Our high retention rates for both intervention activities and follow-up assessments in a sample of couples with low rates of cohabitation indicate that a couples-focused approach is feasible even with non-married and non-cohabitating couples.

Findings support and extend recent studies with couples from similar contexts. First, we focused on improving relationship quality and included communication skills to improve partners' abilities to discuss HIV. Discussions between partners about CHTC increased likelihood of participating in CHTC among couples in rural Uganda[20]. Similarly, Matovu and colleagues [21] reported that motivations for CHTC were relationship-focused (e.g., wanting to increase trust) and recommended that efforts to increase uptake of CHTC similarly engage couples. Second, a couples-based approach facilitates engaging male partners—often identified as a challenge in the SSA context. For example, men may perceive health care clinics as an aversive environment and avoid attending them with their female partners[22]—targeting couples may address this problem. As such, efforts have focused on improving uptake of CHTC by pregnant women and their partners[23]. Finally, the findings mirror the results of a meta-analysis of HIV-related interventions that compared interventions delivered to couples to those delivered to individuals[24]. There was a significant effect for HIV testing given to couples, and the authors emphasized the positive repercussions of CHTC to facilitate mutual serostatus disclosure and as a potential entrée into HIV treatment. We identified more newly diagnosed HIV-positive individuals among couples who participated in CHTC in the intervention group, as compared to the control group (although the difference was not statistically significant), thereby demonstrating the utility of the intervention for individuals missed by other testing efforts.

Findings for sexual behavior were not significant at final follow-up, this reduced sexual risk behavior at first follow-up reflects a common finding of dissipating effects in behavioral prevention trials [25]. Prior recommendations include providing booster sessions to promote continued behavioral risk reduction. Our high retention suggests that couples may be willing to attend additional sessions. Nonetheless, the significant reduction at 3-months post-intervention indicates that the intervention also positively impacted sexual risk behavior in the short term, in addition to its impact on CHTC.

To our knowledge, this is one of the first interventions to use CHTC as its outcome, by comparison, Matovu and colleagues' CHTC intervention only included married or cohabiting couples[26].

CHTC has been praised for its ability to reduce sexual risk behavior and improve disclosure and thus touted as a high-leverage intervention[27] , yet uptake has been relatively low, even in areas where it is widely available[28]. Thus, our intervention represents a step forward in improving uptake. Our outcome measure (CHTC) was conducted and verified by our team, as opposed to being by self-report. Further, our intervention was implemented by members of the local community in conditions reflective of local resources, thereby supporting subsequent implementation[29].

One factor which suggests feasibility for implementation in communities that could benefit from increased HIV testing and linkage to care was the identification and training of lay couples' counselors from the communities themselves. Our utilization of lay counselors, (who typically did not have advanced degrees, but rather had the equivalent of a high-school education ("matric")), coupled with our manualized training increases the feasibility of eventual scale-up for use by community-based organizations or health programs aiming to work with couples. Future efforts should examine whether efficacy translates into effectiveness in non-research settings.

There are some limitations to the results. The intervention and control groups were not time and attention-matched; intervention couples were exposed to more sessions than control couples. However, this design decision was based on the absence of any comparable 'standard of care' pertaining to couples-based services, while balancing the need to provide participants pertinent and helpful information regarding HIV and other health-related issues. Our sexual behavior outcome was based on self-report, and thus subject to social desirability and reporting bias. But this bias is likely the same across arms, therefore only impacting the overall levels of reported sexual behavior. The trial was conducted in a rural community with high migration, high unemployment, and low marriage rates that could affect generalizability to other contexts. Nonetheless, our study contrasts to other couples-based studies in that most studies of CHTC retain samples recruited from HIV clinics, as opposed to community-based settings. Reported IPV rates were low, which is in contrast to other reports from South Africa: figures range from 23% in the Eastern Cape, (as defined by more than one episode of physical or sexual IPV) [30]

to 19.6% of HIV-positive pregnant women reporting physical IPV in Mpumalanga [31].   Although this could limit generalizability to broader samples of couples (e.g., casual partners), few studies have examined violence among committed couples; rather, most focus on women's reports outside of a primary relationship context [30]. Even so, less is known about rates of violence among committed partnerships. It is likely that the study attracted couples with positive relationship dynamics, as they represent those couples most likely to want to participate in a couples-based intervention, indicating a possible selection bias, potentially limiting generalizability. Future research should focus on relationship-based interventions for couples coping with violence in order to improve their ability to participate in CHTC.

CHTC facilitates mutual disclosure, fosters sexual risk reduction, and is a vehicle for treatment referral and engagement for those who test HIV-positive. Our trial provides evidence for the feasibility, acceptability, and efficacy of a couples-based program aimed to increase participation in CHTC among non-traditional couples that have high rates of non-disclosure and low rates of HIV testing. This intervention could serve as the foundation for future preventive behavior, as Delavande and colleagues[32] reported that among a sample of serodiscordant couples repeat HIV testing did not improve seroconversion outcomes, thereby suggesting that one-time testing can be sufficient. Efforts to increase availability of CHTC in urban settings in South Africa have been successful[33], demonstrating that demand for CHTC is not limited to this rural setting. In addition, even as strategies for alternative modes of HIV testing increase (e.g., self-testing), similar barriers remain with regard to partners testing together and disclosing. For example, findings from a community-level HIV self-testing intervention in Malawi found relatively low rates of partners testing together, and described long-standing barriers to testing together-- including fear of a HIV-positive result, wanting to avoid disclosing any infidelity/outside partners, poor communication, and lack of trust [34] . Overcoming these relationship-based barriers was a focus of the Uthando Lwethu intervention.

While general assessments of rates of HIV testing in South Africa have shown increases in numbers of individuals tested for HIV, significant issues remain. Even when tested for HIV, rates of disclosure are low, and we enrolled a significant number of never-tested individuals in a high HIV prevalence area. When considering the WHO guidelines of immediate treatment on diagnosis of HIV the benefits of participating in CHTC are exponentially increased, and underscore the need for increasing its uptake and availability. However, choosing to engage in CHTC can be challenging for couples, and we investigated the utility of influencing the decision-making process by improving communication skills and relationship quality. The findings demonstrate that this approach produced increased mutual disclosure of serostatus for heterosexual couples at increased risk for HIV and could exert a significant impact on public health outcomes in a community substantially burdened by HIV.

Contributors: LD designed the study, obtained the funding, directed the implementation of the study, wrote the first draft of the report, NM contributed to the design of the study, participated in implementation of the study, conducted the statistical analyses, wrote and edited portions of the report, VH, MJ, KF contributed to the design of the study, participated in the implementation of the study, and edited the draft of the report, TN led the implementation of the study, supervised the study staff, edited the report, HVR contributed to the design of the study, directed the implementation of the study, edited the draft of the report.

References

1. Shishana O, Rehle, T., Simbayi, L.S., Zuma, K., Jooste, S., Zungu, N., Labadarios, D., Onoya, D. et al. *South African National HIV prevalence, incidence and behavior survey, 2012.* Cape Town, South Africa2014.

2. South Africa Department of Health. *The 2010 national antenatal sentinel HIV & syphilis prevalence survey in South Africa.* Pretoria2010.

3. Tanser F, Bärnighausen T, Grapsa E, Zaidi J, Newell M. High coverage of ART associated with decline in risk of HIV acquisition in rural KwaZulu-Natal, South Africa. *Science (New York, NY.* 2013;339(6122):966-971.

4. Haber N, Tanser, F., Bor, J., Naidu, K., Mutevedzi, K., Herbst, K., Porter, K., Pillay, D., & Barnighausen, T. From HIV infection to therapeutic resopnse: a population-based longitiudinal cascade-of-care study in KwaZulu-Natal, South Africa. *The Lancet HIV.* 2017;4(5):e223-e230.

5. Matthews LT, Moore, L., Crankshaw, T.L., Milford, C., Mosery, F.N., Greener, R., ...Smit, J. A. . South Africans with recent pregnancy rarely know partner's HIV serostatus: Implications for serodiscordant couples interventions. *BMC public health.* 2014;14:843.

6. McGrath N, Richter, L., & Newll, M.L. Sexual risk after HIV diagnosis: a comparison of pre-ART individuals with CD4>500 cells/ul and ART-eligible individuals in a HIV treatment and care programme in rural KwaZulu-Natal, South Africa. . *Journal of the International AIDS Society.* 2013;16:18048.

7. Dunkle KL, Stephenson R, Karita E, et al. New heterosexually transmitted HIV infections in married or cohabiting couples in urban Zambia and Rwanda: an analysis of survey and clinical data. *Lancet.* 2008;371(9631):2183-2191.

8. Burton J, Darbes L, Operario D. Couples-focused behavioral interventions for prevention of HIV: A systematic review of the state of the evidence. *AIDS and behavior.* 2010;14(1):1-10. doi: 10.1007/s10461-10008-19471-10464.

9.   Hosegood V, McGrath N, Moultrie T. Dispensing with marriage: Marital trends in rural KwaZulu-Natal, South Africa 2000-2006. *Demographic Research.* 2009;20(13):279-312.

10.   World Health Organization. *Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples.* Geneva, Switzerland: WHO;2012.

11.   Allen S, Meinzen-Derr J, Kautzman M, et al. Sexual behavior of HIV discordant couples after HIV counseling and testing. *AIDS (London, England).* 2003;17(5):733-740.

12.   Rosenberg NE, Graybill, L.A., Wesevich, A., McGrath, N., Golin, C.E., Maman, S., Bhushan, N., Tsidya, M., Chimndozi, L., Hoffman, I.F., Hosseinipour, M.C., & Miller, W.C. The impact of couple HIV testing and counseling on consistent condom use among pregnant women and their male partners: an observational study. *J Acquir Immune Defic Syndr Hum Retrovirol.* 2017;75(4):417-425.

13.   Wall KM, Kilembe, W., Vwalika, B., Haddad, L.B., Lakhi, S., Onwubiko, U., Htee Khu, N., Brill, I., Chavuma, R., Vwalika, C., Mwananyanda, L., Chomba, E., Mulenga, J., Tichacek, A., Allen, S. Sustained effect of couples' HIV counselling and testing on risk reduction among Zambian HIV serodiscordant couples. *Sex Trans Infect* 2017;93(4):259-266.

14.   Leddy A, Chakravarty, D., Dladla, S., de Bruyn, G., & Darbes, L.A. Sexual communication self-efficacy, hegemonic masculine norms and condom use among heterosexual couples in South Africa. *AIDS care.* 2016;28(2):228-233.

15.   Pettifor A, MacPhail, C., Nguyen, N, Rosenberg, M., Parker, L. & Sibeko, J. . Feasibility and acceptability of Project Connect: A couples-based HIV-risk reduction intervention among young couples in Johannesburg, South Africa. *AIDS care.* 2014;26(4):476-482.

16.   Bhatia DS, Harrison, A.D., Kubeka, M., Milford, C., Kaida, A., Bajunirwe, F., Wilson, I.B., Psaros, C., Safren, S.A., Bangsberg, D.R., Smit, J.A., & Matthews, L.T. . The role of relationship dynamics and gender inequalities as barriers to HIV serostatus disclosure: Qualitative study among women and men living with HIV in Durban, South Africa. *Front Public Health.* 2017;5.

17.   Rogers AJ, Achiro, L., Bukusi, E.A., Hatcher, A.M., Kwena, Z., Musoke, P.L., Turan, J.M., Weke, E., & Darbes, L.A. Couple interdependence impacts HIV-related health behaviors among pregnant couples in southwestern Kenya: a qualitative analysis. *J Int AIDS Soc.* 2016;19(1).

18.   Darbes L, Van Rooyen H, Hosegood V, et al. Uthando Lwethu ('our love'): a protocol for a couples-based intervention to increase testing for HIV: a randomized controlled trial in rural KwaZulu-Natal, South Africa. *Trials.* 2014;15(64):doi:10.1186/1745-6215-1115-1164.

19.   Markman HJ, Renick MJ, Floyd FJ, Stanley SM, Clements M. Preventing marital distress through communication and conflict management training: a 4- and 5-year follow-up. *Journal of consulting and clinical psychology.* 1993;61(1):70-77.

20.   Muhindo R, Nakalega, A., Nankumbi, J. Predictors of couple HIV counseling and testing among adult residents of Bukomero sub-countym Koboga district, rural Uganda. *BMC public health.* 2015;15:1171.

21.   Matovu JK, Wanyenze, R.K., Wabwire-Mangen, F., Nakubulwa, R., Sekamwa, R., Masika, A., Todd, J., & Serwadda, D. "Men are always scared to test with their partners...it is like taking them to the Police": Motivations for and barriers to couples' HIV counselling and testing in Rakai, Uganda: a qualitative study. *J Int AIDS Soc.* 2014;17.

22.   Ladur AN, Colvin, C.J., Stinson, K. Perceptions of community members and healthcare workers on male involvement in prevention of mother-to-child transmission services in Khayelitsha, Cape Town, South Africa. *PLoS ONE.* 2015;10(7).

23.   Rosenberg NE, Mtande, T.K., Saidi, F., Stanley, C., Jere, E., Paile, L., ...Hosseinipour, M. . Recruiting male partners for couple HIV testing and counselling in Malawi's option B programme: An unblinded randomised controlled trial. . *The Lancet HIV.* 2015;2(11):e483-e491.

24.   Crepaz N, Tungol-Ashmon, M.V., Vosburgh, H.W., Baack, B.N., & Mullins, M.M. Are couple-based interventions more effective than interventions delivered to individuals in promoting HIV protective behaviors? A meta-analysis. *AIDS care.* 2015;27(11):1361-1366.

25.   Team HLP. Effects of a behavioral intervention to reduce risk of transmission among people living with HIV: The Health Living Project randomized controlled study. *J Acquir Immune Defic Syndr Hum Retrovirol.* 2007;44(2):213-221.

26.   Matovu JK, Todd, J., Wanyenze, R.K., Kairania, R., Serwadda, D., & Wabwire-Mangen, F. Evaluation of a demand-creation intervention for couples' HIV testing services among married or cohabiting individuals in Rakai, Uganda: a cluster-randomized intervention trial. *BMC Infec Disease.* 2016;16(379).

27.   Medley A, Baggaley R, Bachanas P, Cohen MS, Shaffer N, Ying-Ru L. Maximizing the impact of HIV prevention efforts: Interventions for couples. *AIDS care.* 2013;In Press.

28.   Naik R, Tabana H, Doherty T, Zembe W, Jackson D. Client characteristics and acceptability of a home-based HIV counseling and testing intervention in rural South Africa. *BMC public health.* 2013;12:824.

29.   Tunis S, Stryer, D., Clancy, C. Practical clinical trials: Increasing the value of clinical research for decision making in clinical and health policy. *JAMA.* 2011;290(12):1624-1623.

30.   Jewkes R, Dunkle, K., Nduna, M., & Shai, N. Intimate partner violence, relationship power inequity, and incidence of HIV infection in young women in South Africa: a cohort study. *The Lancet.* 2010;376(9374):41-48.

31.   Matseke G, Rodriguez, V.J., Peltzer, K., & Jones, D. Intimate partner violence among HIV-positive pregnant women in South Africa. *J Psychol Afr.* 2016;26(3):259-266.

32.   Delevande A, Wagner, Z., & Sood, N. The impact of repeat HIV testing on risky sexual behavior: evidence from a randomized controlled trial in Malawi. *Journal of AIDS Clin Research.* 2016;7(3).

33.   Kilembe W, Wall, K.M., Mokgoro, M., Mwaanga, A., Dissen, E., Kamusoko, M., ...Allen, S. Implementation of couples' voluntary HIV counseling and testing services in Durban, South Africa. *BMC public health.* 2015;15.

34.   Kumwenda MK, Corbett, E.L., Chikovore, J., Phiri, M., Mwale, D., Choko, A.T., Nliwasa, M., Sambakunsi, R., Taegtmeyer, M., Gutteberg, T.J., Munthali, A., & Desmond, N. . Discordance, disclosure and normative gender roles: Barriers to couple testing within a community-level HIV self-testing intervention in urban Blantyre, Malawi. . *AIDS and behavior.* 2018.

Figure 1

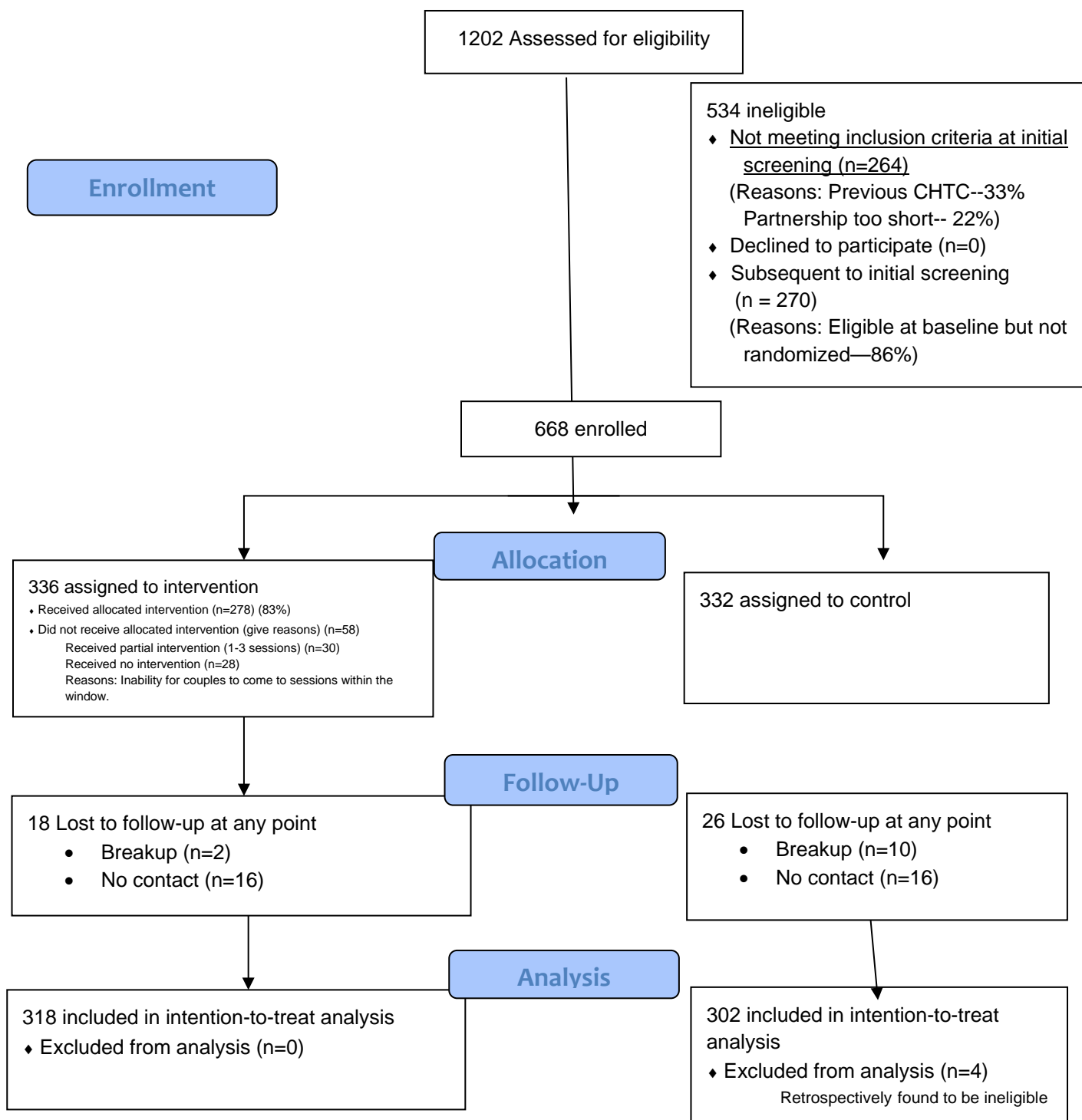Consort Diagram for Uthando Lwethu

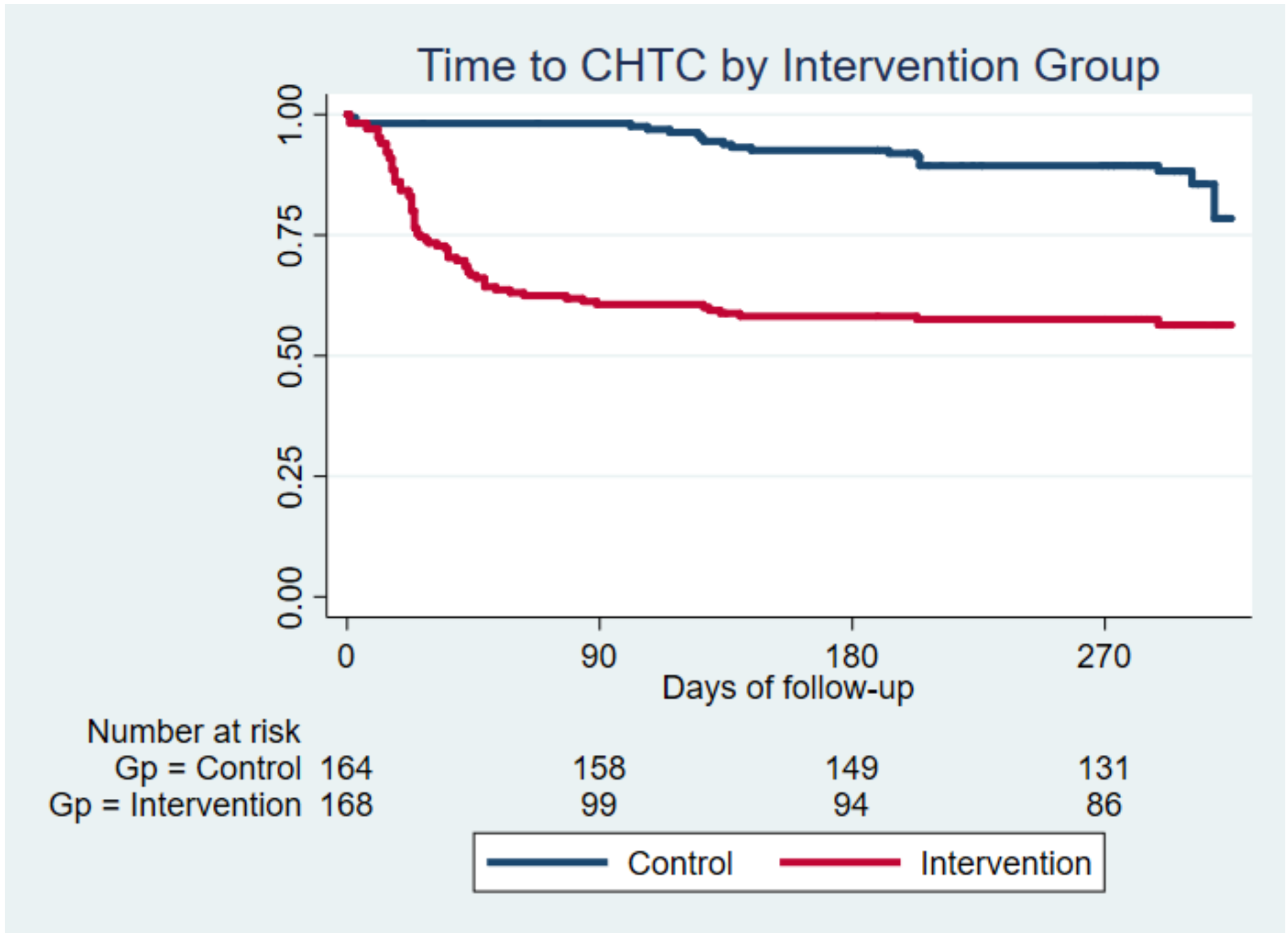Figure 2   Kaplan Meier plot: Time to CHTC by intervention group

Time to CHTC by Intervention Group

Number at risk
Gp = Control 164   158   149   131
Gp = Intervention 168   99   94   86

Table 1 Baseline characteristics

Individuals (N = 664)	Control (n = 328)	Intervention (n = 336)
Demographics		
Age (in years)*	27 (23-35)	26 (22-31)
Women	26 (21-32)	24 (21-31)
Men	28 (24-36.5)	27 (23-32)
Highest education is matric or higher	42% (139)	44% (149)
Employed	23% (77)	20% (68)
Married to study partner*	23% (77)	20% (68)
Co-resident with study partner (12 missing)	23% (73)	18% (61)
Population group is African	100% (328)	99.4% (334)
Length of relationship with study partner (in years)	3 (2-6)	3 (2-5.1)
Sexual Behavior		
Lifetime partners among those who reported ever had vaginal sex	3 (2-7)	3 (2-5)
Of whom: A condom was used at last sex with study partner:		
Yes	45% (147)	49% (163)
No	55% (179)	51% (173)
Don't know	0.6% (2)	—
Has had sex with a non-study partner in the 3 months before baseline		
Male		
Yes	6% (10)	4% (7)
No	94% (154)	96% (161)
Female		
Yes	0.6% (1)	—
No	99.4% (163)	100% (168)
# of other partners		
Male		
1 partner	7	5
2 partners	2	2
Female		
1 partner	1	—
Alcohol use: frequency of 'binge' drinking		
Never	82% (270)	80% (268)
Less than monthly	9% (31)	12% (40)
Monthly	6% (19)	6% (21)
Weekly	2% (8)	2% (7)
HIV Testing Status		
Has ever been tested for HIV:		

Males		
Yes	59% (96)	63% (105)
No	41% (67)	37% (63)
Don't Remember	0.6% (1)	—
Females		
Yes	63% (103)	60% (101)
No	37% (61)	40% (67)
Don't Remember	—	—
Of whom test was within 12 months of baseline:		
Yes	72% (143)	76% (154)
No	28% (56)	24% (48)
Of whom tested and were willing to share their results: HIV status at most recent test:	85% (170)	85% (176)
HIV+	15% (26)	14% (24)
HIV-	85% (144)	86% (152)
Of whom has disclosed most recent HIV test result to someone:		
Yes	41% (81)	37% (77)
No	59% (118)	63% (129)
Of whom study partner knows the result of any HIV test:		
Yes	24% (48)	20% (41)
No	73% (146)	73% (151)
Tried to tell, but unsuccessful	1.5% (3)	2.4% (5)
Not sure	1% (2)	4.4% (9)
Intimate Partner Violence		
Male		
Victim of physical violence:		
Ever in last 6 months	—	1.2% (2)
Ever prior to 6 months	4.9% (8)	5.4% (9)
Victim of sexual violence:		
Ever prior to 6 months	0.6% (1)	—
Victim of emotional abuse:		
Ever in last 6 months	3.7% (6)	0.6% (1)
Ever prior to 6 month	3.7% (6)	3.6% (6)
Perpetrator of physical violence:		
Ever in last 6 months	—	1.2% (2)
Ever prior to last 6 months	4.9% (8)	5.4% (9)
Perpetrator of sexual violence:		
Ever prior to 6 months	0.6% (1)	—
Perpetrator of emotional abuse:		
Ever in last 6 months	3.7% (6)	0.6% (1)
Ever prior to last 6 months	3.7% (6)	3.6% (6)
Female		
Victim of physical violence:		
Ever in last 6 months	—	0.6% (1)
Ever prior to 6 months	0.6% (1)	—
Victim of sexual violence:		
Ever prior to 6 months	0.6% (1)	—
Victim of emotional abuse:		

	Control	Intervention
Ever in last 6 months	0.6% (1)	1.2% (2)
Ever prior to 6 month	1.2% (2)	—
Perpetrator of physical violence:		
Ever in last 6 months	—	0.6% (1)
Ever prior to last 6 months	0.6% (1)	—
Perpetrator of sexual violence:		
Ever prior to 6 months	0.6% (1)	—
Perpetrator of emotional abuse:		
Ever in last 6 months	0.6% (1)	1.2% (2)
Ever prior to last 6 months	1.2% (2)	—

Couples (N = 332)	Control (n = 164)	Intervention (n = 168)
Demographics		
Cohabitation status		
Cohabiting	26% (41)	21% (35)
Not cohabiting	74% (119)	79% (132)
Shared a pregnancy together		
Yes – both partners agree	36% (59)	37% (62)
No – both partners agree	52% (86)	57% (96)
Couple does not agree	12% (19)	6% (10)
Couple marital status		
Agree, married	13% (21)	8% (13)
Agree, not married	87% (143)	92% (155)
Employment status		
Both employed	4% (6)	3% (5)
Neither employed	57% (93)	63% (105)
Male employed	32% (53)	30% (51)
Female employed	7% (12)	4% (7)
Sexual Behavior		
Condom use at last sex		
Yes condom used – both partners agree	35% (58)	39% (65)
No condom used – both partners agree	45% (74)	42% (70)
Couple disagree	18% (30)	20% (33)
One or both missing/refused to answer	1.2% (2)	—
HIV Testing		
Both partners HIV tested	41% (67)	41% (69)
Female partner HIV tested only	21% (35)	19% (32)
Male partner HIV tested only	18% (29)	21% (36)
Neither partner HIV tested	20% (32)	18% (31)
One or both don't remember	—	—
Outside Partners		
Neither has outside partner	93% (153)	96% (161)
Male has outside partner	6% (10)	4% (7)
Female has outside partner	0.6% (1)	—

Table 1. Baseline characteristics for individuals and couples.

*significant group differences p $\leq$ 0.05

Table 2 HIV Serostatus for couples that participated in CHCT

Couples (N = 332)	Control (n = 164)	Intervention (n = 168)
Participated in CHCT	12% (20)	42% (71)
Concordant HIV-negative	55% (11)	46% (33)
Concordant HIV-positive	30% (6)	30% (21)
HIV discordant	15% (3)	24% (17)