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## Stronger Together: Results from a Randomized Controlled Efficacy Trial of a Dyadic Intervention to Improve Engagement in HIV Care Among Serodiscordant Male Couples in Three US Cities

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Compliance with Ethical Standards

**Ethical Approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval for this study was obtained from the Institutional Review Boards of Emory University (IRB #00065111), Lurie Children's Hospital (IRB #2014–15896) and The Fenway Institute (IRB #FWA00000145). The authors declare no conflicts of interest. Informed consent was obtained from all participants via an electronic consent form.

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## Abstract

Engagement in HIV care and a high level of antiretroviral therapy (ART) adherence for people living with HIV is crucial to treatment success and can minimize the population burden of the disease. Despite this, there is a critical gap in HIV prevention science around the development of interventions for serodiscordant male couples. This paper reports on the results of a randomized controlled trial to assess the efficacy of *Stronger Together*, a dyadic counseling intervention aimed at increasing engagement in and optimizing HIV care among serodiscordant male couples in Atlanta, GA, Boston, MA, and Chicago, IL. Between 2014 and 2017, 159 male serodiscordant couples (total N = 318) in Atlanta, GA, Boston, MA, and Chicago, IL were enrolled and equally randomized to either the Stronger Together intervention arm (a three-session dyadic intervention involving HIV testing and adherence counseling) or a standard of care (SOC) control arm. Couples completed individual study assessments via an audio computer assisted self-interviewing (ACASI) system at baseline, 6, 12 and 18 months. Primary outcomes included being prescribed and currently taking ART, and fewer missed doses of ART in the past 30 days; because the trial was not powered to examine viral suppression, we examined this as an exploratory outcome. Longitudinal data analysis was by an intention-to-treat approach. Participants ages ranged from 18 to 69 (mean = 35.9), and are predominantly white (77.5%), and college educated (68.4% earned a college degree or higher). Participants randomized to the *Stronger Together* arm had a significantly greater odds of being prescribed and currently taking ART over time than those in the SOC arm (at 12 months OR 2.75, 95% CI 1.35–4.67, p-value 0.020, and at 18 months OR 2.91, 95% CI 1.61–4.88, p-value 0.013). Similarly, those in the Stronger Together arm had a significantly lower odds of missing a dose of ART in the past 30 days over time compared to those in the SOC arm (at 12 months OR 0.28, 95% CI 0.09–0.81, p-value 0.019, and at 18 months OR 0.25, 95% CI 0.07–0.82, p-value 0.023). Among male couples in serodiscordant relationships, the *Stronger Together* intervention resulted in significantly improved HIV treatment outcomes at both 12 and 18 months of follow-up. This trial is the first to date to demonstrate evidence of efficacy for a dyadic counseling intervention and has the potential to fill a critical gap in secondary HIV prevention interventions for serodiscordant male couples.

## Keywords

Couples; Adherence; Testing; Behavioral interventions

## Introduction

For gay, bisexual, and other men who have sex with men (GBMSM), HIV prevention has predominantly emphasized HIV risks in the context of casual sex, largely ignoring the risk of HIV transmission that may occur within primary partnerships. Recent evidence has demonstrated the fallacy of ignoring male partnerships in HIV prevention: modeling work has identified primary partners as the source of approximately one-third [1] to two-thirds [2] of new HIV infections among GBMSM. High levels of transmission within main partnerships have been attributed to a higher number of sex acts with main partners, more frequent receptive roles in anal sex, and lower condom use during anal sex with main

partners [1–4]. Additionally, partnered GBMSM often perceive themselves to be at lower risk of HIV infection [5, 6] and are less likely to test routinely for HIV [7, 8]. These findings support the need to develop interventions that teach male dyads to work together to plan and manage HIV risks in their main partnership.

Serodiscordant male couples, in which one partner is HIV-positive and the other is HIV-negative, represent a high priority group for intervention, with dual, synergistic needs for HIV prevention and care. There is now clear evidence that the risk of HIV transmission through condomless anal intercourse (CAI) when the HIV-positive partner is virally suppressed is effectively zero [9–15]. However, attaining the standard of undetectable equals untransmittable (U=U) as a bio-behavioral risk reduction strategy rests on the HIV-positive member of dyad having functional knowledge of the relationship between ART adherence and viral suppression, and the skills and circumstances necessary to adhere to ART sufficiently to remain virally suppressed. Approximately 95% ART adherence is the threshold required to achieve viral suppression—a threshold that is considerably higher than levels of medication adherence observed in many of the observational studies that have examined the impact of viral suppression on HIV progression and transmission [16–19]. Though a wide range of adherence rates (53–89%) have been documented in varied populations [17, 20–29], the average rate of ART adherence is thought to be approximately 70% in the US [30]. For serodiscordant male couples, ART adherence and achieving and sustaining viral suppression should be considered a priority for protecting the health of both partners. Couples may be abandoning condom use due to the perceived benefits of U=U, and negative partners may be adopting pre-exposure prophylaxis (PrEP), but need to make these prevention decisions based on up-to-date information on viral suppression of the positive partner, and also need to have the communication skills necessary to discuss HIV prevention as a dyad.

Given the critical context of main partnerships in HIV transmission, recent research and intervention efforts have focused on developing interventions that teach male couples the skills required for active engagement in HIV prevention and care [6, 31–34]. Within the US, interventions for male couples have largely focused on the joint provision of HIV counseling and testing—focusing on giving couples the skills to engage in HIV prevention. Labeled as a high leverage HIV prevention intervention by the US Centers for Disease Control and Prevention (CDC), Couples HIV Testing and Counseling (CHTC), where both partners receive HIV counseling and testing together, is considered to be an effective approach to HIV prevention among male couples [35, 36]. A critical aspect of CHTC involves couples discussing their sexual agreements, the mutually understood rules between two main partners that describe the kinds of sexual behavior that is allowed within and outside of the relationship [37–39]. Sexual agreements are shown to be both common among male couples, with 58% [40] to 99% [41] of partnered GBMSM reporting a sexual agreement, with couples often revisiting and making changes to their agreement over the course of their relationship [39, 42]. Sexual agreements are considered protective against sexual risk-taking behaviors, with greater investment in a sexual agreement being associated with lower rates of unprotected anal intercourse (UAI) with outside partners [43, 44], as well as offering an opportunity to enhance intimacy, pleasure, and reciprocal trust within relationships [31].

There is strong evidence that male couples can work together to achieve HIV prevention and care goals. In a randomized controlled trial (RCT) of 215 couples, including but not exclusively male couples, HIV-positive persons receiving ART adherence counseling with their partners had significantly higher levels of ART adherence than those who did not [45]. Social support among HIV-positive persons, including support from primary partners, is associated with fewer reported HIV risk behaviors with outside partners, greater self-efficacy to adhere, reported adherence, and lowered viral load after six months of follow-up [46, 47].

However, despite evidence that male couples can work together on issues of HIV prevention, there is a critical gap in prevention science around the development of interventions tailored to the unique needs of serodiscordant male couples [48]. Serodiscordant couples require education and access to resources for both HIV prevention and care, while to date interventions for male couples have focused on concordant negative couples, engaging them both in HIV prevention. This paper reports on the results of a randomized controlled trial to assess the efficacy of *Stronger Together*, a dyadic counseling intervention aimed at increasing engagement in and optimizing HIV care among serodiscordant male couples in Atlanta, GA, Boston, MA, and Chicago, IL. The intervention draws upon two efficacious strategies to create a couples-focused package of care that incorporates dyadic HIV testing (CHTC) with dyadic adherence counseling, which addresses both individual and structural level barriers. The intervention focuses on a couples-focused continuum of care, in which the couple is tested together and receives ART adherence counseling together, compared to a standard of care (SOC) in which couples received individual HIV counseling and testing alone.

## Methods

### Participants and Procedures

**Study Design**—The intervention, *Stronger Together*, was evaluated through an RCT, conducted in three US cities (Atlanta, Boston, and Chicago). Ethical approval was obtained from Emory University (IRB #00065111), Lurie Children’s Hospital (IRB #2014–15896) and The Fenway Institute (IRB #FWA00000145) Institute Institutional Review Boards. The study was registered on [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01772992) (NCT01772992) before initiating study recruitment. Additional details on procedures and intervention have been published previously [36, 49]. Cohort recruitment began in 2014 and the final follow-up visit was completed in December 2018. 159 male serodiscordant couples (total N = 318 individuals) were enrolled and equally randomized to either the *Stronger Together* intervention arm (a three-session dyadic intervention involving HIV testing and adherence counseling) or a SOC arm. Couples were followed prospectively for 18 months, with study assessments at baseline, 6, 12, and 18 months.

**Participants**—Eligible participants were cisgender male couples in which two men: (1) reported having been in a relationship with each other for greater than one month, with a relationship defined as “*having a male partner who you are committed to above all others,*” (2) were both aged over 18 years, (3) lived in the Atlanta, Boston or Chicago metro area for

greater than 3 months, (4) reported no recent history (in the past 12 months) of IPV or coercion, and (5) were in an HIV serodiscordant relationship in which both partners have disclosed their serostatus to each other. Prevalent HIV seropositive statuses were confirmed by study staff.

**Recruitment**—Participants were recruited from the Atlanta, Boston and Chicago metro areas, via a multi-modal recruitment strategy. Recruitment occurred in physical and online/virtual spaces. Online sources included advertising on social media (e.g. Facebook) and on geospatial dating apps (e.g. Grindr). In-person recruitment was achieved by study staff attending LGBT events, visiting venues, meeting potential participants at clinic appointments and posting flyers in gay-themed venues. All recruitment activities provided individuals with the study uniform resource locator (URL). Men expressing interest in participation were directed to the study screening consent form, and if they consented to be screened, were then directed to a short eligibility screener. Men who (1) did not consent or (2) did not meet the eligibility criteria were taken to a screen thanking them for their interest. Eligible men were directed to a registration process. During the registration process they provided their name, email address and a cell phone number. They were also given the option to provide their main partner’s e-mail address and/or cell phone number so they could be contacted and screened in order to enroll the couple in the study. Once both partners had (1) completed the screening consent forms, (2) finished the screening questionnaire, (3) were deemed eligible for the study, and (4) provided contact information, a staff member contacted the couple to schedule the couple for an in-person baseline visit.

**Enrollment Procedures and Baseline Assessment**—When an eligible couple came in for a baseline visit, they were assigned a couple ID number and administered a “Check In” survey. This survey generated a randomization number, confirmed eligibility, verified the couple was a real couple, and gathered further contact information and alternative contacts for the participant. If a couple was no longer eligible or were determined not to be partnered, they were dismissed without study staff specifying why in order to avoid instigating IPV or revealing eligibility criteria. Eligible couples were taken into separate rooms for the consent process. An informed consent process was administered using a written form and orally by study staff; if one or both members of the couple declined consent, the couple was dismissed without study staff specifying eligibility criteria. For couples in which both partners consented, before randomization to either the intervention or SOC group was revealed to the couple or staff members interacting with the participants, each member of the couple was given a baseline survey. This survey took approximately 60–90 min to complete, and it collected data on demographics, relationship characteristics, sexual history, HIV care, and HIV prevention.

**Randomization**—Upon completion of the check-in survey by both partners, couples were equally randomized to receive the *Stronger Together* intervention or SOC arms. The treatment assignments were generated with the use of one pseudo-random-number generator across all three study sites.

**Stronger Together (Intervention)**—The intervention was a combination of CHTC and medication adherence counseling through the Partner STEPS method [49], a dyadic adaptation of Life Steps, an existing cognitive-behavioral intervention for individuals [50]. The intervention was comprised of three in-person counseling sessions. In the first session, lasting between 30 and 45 min, couples received CHTC. The second and third sessions, lasting 60 min each, were held 8 and 10 weeks after the CHTC session, during which couples received dyadic focused ART adherence counseling. At the 6-, 12-, and 18-month follow up visits, couples also received CHTC and Partner STEPS booster sessions.

**Theoretical Basis for Intervention**—The intervention is grounded in Couple's Interdependence Theory [51], a framework that combines both interdependence theory and communal coping perspectives. The framework guides the selection of measures of behaviors and behavior change within the couple. These measures relate to our intervention in two ways. First, some aspects of communication and decision-making within the partnership may influence the efficacy of the intervention; couples with more constructive communication styles may benefit more from CHTC and achieve greater linkage to and retention in HIV care than couples with less constructive communication styles. Second, some aspects of partnerships, such as efficacy around implementing behavioral change, may actually be modified by the intervention. In this case, changes in key characteristics of the partnerships may be in the causal pathway between the intervention and the adoption of ART, linkage to care, and safer behaviors within the partnership. We thus conceptualized the causal pathways as follows. Couples exposed to the intervention package will receive opportunities to talk about HIV, safer sex, and care-seeking within their relationship jointly with a qualified CHTC counselor. Relative to couples exposed to the SOC, exposure to CHTC may, in turn, impact communal coping, use of coping, and transformation of motivation, leading to initiation and maintenance of health-enhancing behaviors, (which we conceptualize as greater uptake and retention in care and ART adherence).

**Session One, CHTC**—CHTC sessions were conducted by a bachelors-level counselor (interventionist) who was trained in CHTC and lasted approximately 30–45 min. CHTC training was conducted by RS and PS. A 2-day training was provided, in which interventionists learned CHTC skills through a combination of didactic learning and role play. Only the HIV negative partner was tested during the session, but both partners were present for the whole session. Post-test counseling focused on dyadic prevention messages, and revisited the couple's HIV risk concerns and sexual agreements in light of their test results. While focusing on the needs of the HIV-positive partner is necessary, the discussion also emphasized how the couple can work together to keep the positive partner healthy and reduce transmission risks within the relationship. The prevention counseling element of the CHTC session focused on talking to the couple about prevention options—including PrEP—and asking them to consider which prevention options may work best based on their relationship needs, context, and unique risk profile.

**Sessions Two and Three, Partner Steps**—Bazzi et al., describe the protocol for the developing and testing of the Partner STEPS intervention [49]. Couples in the intervention arm attended two additional visits (Partner Steps) consisting solely of adherence counseling

at 8 and 10 weeks after their first CHTC visit. Based on the efficacious Life Steps intervention [50], Partner STEPS [49] used motivational interviewing to improve ART adherence among HIV-positive individuals, by creating strategies for couples to work together on shared goals. The Partner STEPS intervention was developed by drawing from relationship-oriented theory, existing efficacious individual-level ART adherence interventions, couple-focused HIV prevention interventions, and expert consultation. New content to address all aspects of the HIV care continuum (e.g. linkage to and retention in care) and to draw on relationship strengths through interactive activities was incorporated. The theory-based Partner Steps intervention was delivered by the same counselor who delivered the CHTC session—to ensure continuity in intervention provision. Each session was designed to use relationship strengths to increase motivation for HIV care and treatment and cover sequential intervention “steps” relating to specific challenges in HIV care engagement and barriers to ART adherence. For each step, couples worked with the counselor to identify their unique challenges, actively problem-solve with the counselor, and articulate and commit to working together to implement a plan in which each partner agrees to complete specific tasks. Partner Steps counseling focused on dyadic strategies to improve medication adherence and retention in care at each of ten “steps” for which Partner STEPS is named.

Each step is a portion of HIV care that can present a challenge to those seeking care. The ten steps are: (1) transportation to appointments, (2) obtaining medications, (3) communicating with providers, (4) storing and transporting medications, (5) having a daily medication schedule, (6) coping with side effects, (7) adherence, self-care and your relationship, (8) communicating within your relationship, (9) managing your social life and other relationships, and (10) dealing with privacy and disclosure. Counselors were trained by AB, MM and MH through a 2-day training in which interventionists role-played the intervention and received feedback from trainers. The counselors were trained to keep focus on the couple by engaging both partners in problem solving and plan development. Counselors were trained to focus discussion on how *both partners can work together* to keep the positive partner healthy and to prevent transmission to the negative partner through medication adherence. This included training the interventionists to engage both members of the dyad at all stages of the discussions, and to ask participants to reflect and react to the comments made by their partner. Strategies to improve medication adherence and retention in care were tailored to the couple’s unique relationship, and the counselor asked the couple to consider strategies that may work best based on their relationship needs, context, and unique health situation.

**Standard of Care (SOC) Control**—Couples in the control group received only one intervention visit, the content of which included only the current SOC for individuals. At the baseline visit, the HIV-negative partner in the SOC received individual HIV counseling, testing, and referral (CTR). The HIV positive partner received information on the importance of ART uptake and adherence. HIV positive partners were provided with an iPad on which to read information on ART uptake and adherence, while they waited for their partner to complete their CTR session. Couples in the control arm did not receive Partner STEPS adherence counseling.



**Follow-up Assessments**—Couples completed individual study assessments via an audio computer assisted self-interviewing (ACASI) system at baseline, 6, 12 and 18 months. These visits also consisted of biological sample collection, and either CTR for the HIV-negative partner in the SOC arm, information on adherence to ART for the HIV positive partner in the SOC arm (but not counseling on adherence) or CHTC and Partner STEPS counseling for the intervention couples. CHTC was offered to SOC arm couples at the 18-month study visit.

**Incentives**—Individual participants received \$50 for completing each study visit at baseline, 6, 12 and 18 months. The total incentive amount was \$400 per couple (\$200 per individual participant).

**Couple Dissolution**—For couples who dissolved their relationship during the course of the follow-up period, the HIV-positive partner was retained in the study for the full 18 month follow up period while negative partners returned for one more follow up visit and then were censored from the cohort.

**Fidelity Monitoring**—Fidelity of the intervention delivery was supported using approaches recommended by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium [52]. Interventionists received booster trainings throughout the follow-up period, and met with RS, PS, MM, MH and AB to discuss and problem-solve issues that arose during counseling sessions.

**Measures of Engagement in HIV Care**—Participants were asked to self-report their number of clinical care visits in the past 12 months, whether a viral load test was conducted at that visit, whether they had missed any clinical care visits (and the reason for missing the visit), whether they were currently prescribed and taking ART and a self-reported measure of ART adherence, using the Visual Analog Scale [53]. For HIV-negative partners, HIV serostatus was tested at each study assessment using a HIV rapid test.

**Viral Load Testing**—Blood samples were drawn from all HIV-positive partners at baseline, 6, 12 and 18 months: viral load tests were performed using the Abbot Real Time HIV-1 Assay on the Abbott m2000 sample preparation/Abbott m2000 real time analyzer system (Abbott Molecular Inc., Des Plaines, IL) using the 0.6 plasma protocol.

## Statistical Analysis

For primary analysis examining whether the intervention was successful in increasing engagement in HIV care for the positive partner by the final follow-up assessment, our initial power analysis (power of 80% and  $\alpha = 0.05$  based on detecting differences in self-reported ART adherence) assumed 200 HIV-positive partnered men (400 participants (200 HIV positive and 200 HIV negative) or 200 couples) at baseline. However, this recruitment target assumed an attrition rate of 20% due to relationship dissolution and 15% loss to follow-up due to other causes, for an estimated final sample size of approximately 140 HIV positive men with HIV negative male partners. Ultimately, the RCT randomized 159 HIV positive men and their HIV negative male partners.

The analysis considers three primary engagement in HIV care outcomes for which we a priori determined a sample size to achieve statistical power above 80% and one exploratory outcome, viral load suppression, for which we were not powered and did not include as a study outcome. The three primary outcomes include: (1) currently prescribed ART and taking the ART, (2) attending at least one HIV clinical care visit in the past six months, and (3) whether the participant reports missing more than one dose of ART in the past 30 days.

The analyses followed an intention-to-treat approach. The percentage of HIV-positive individuals who achieved each of the engagement in HIV care outcomes was compared across study arms, using Chi-square test for significant difference. Separate longitudinal regression models were fit for each of the primary and exploratory binary outcomes. Models were estimated using generalized estimating equations (GEE) with robust standard error estimates, which provide an extension of regression analysis to the case of repeated observations and allow for inclusion of both categorical and count-dependent variables and for appropriate modeling of covariance structures when observations are correlated over time. The models contained terms for intervention group assignment, time, and their interaction; a significant effect for the interaction indicates differences in the change of the outcomes from baseline to follow-up for the treatment groups.

## Results

Figure 1 displays the consort diagram for the Stronger Together RCT. In total, 4624 men took the online screener, of whom 1264 completed the screener (27%) and 999 (79%) of those who completed the screener were eligible. Main reasons for ineligibility were self-reporting being in a seroconcordant negative relationship (111, 42%), not being interested in participating (47, 18%) and reporting recent (12 months) intimate partner violence (IPV) (17, 6%). Of the 999 eligible, 395 (40%) did not schedule a study visit: hence 604 individuals (302 couples) attended the baseline visit. During the baseline visit, 132 seroconcordant negative couples (264 individuals) were identified and excluded from the RCT. A further 22 individuals (11 couples) were deemed ineligible at the baseline visit: 12 (55%) of these failed to pass the couples' verification test (their answers on the nature and characteristics of their relationship, such as reporting their partner's birth month or the number of pets he owns, did not match). This resulted in 159 serodiscordant couples enrolled into the prospective RCT.

Retention rates were high: 86% (137 HIV positive men/ serodiscordant couples) at 6 months and 77% (123 HIV positive men/ serodiscordant couples) at 12 and 18 months. All participants randomized to the intervention arm attended all three required intervention sessions if the relationship did not dissolve before intervention completion, indicating high participant acceptability. In total, 27 (17%) couples dissolved their relationship during the course of the RCT, but 90% of the HIV positive partners of dissolved couples were retained for follow-up through the 18 months study assessment.

Table 1 shows the demographic, behavioral, and HIV engagement in care characteristics of the HIV positive men enrolled in the RCT. The mean age of the sample was 40 years (range 18–69: intervention mean 40 years, SOC mean 39 years), the majority identified as White

(intervention 68.7%, SOC 63.2%) and gay (intervention 93.4%, SOC 88.6%) and reported fulltime employment (intervention 78.8%, SOC 87.3%). Participants reported relatively high levels of syndemic risks for disengagement from HIV care: more than one-third reported being arrested in the past 12 months (intervention 36.2%, SOC 43.0%), and the reported prevalence of recent binge drinking (intervention 47.5%, SOC 46.8%) and substance use (intervention 23.8%, SOC 22.8%) was relatively high. In this sample of HIV positive men with known HIV negative partners, a significant proportion reported CAI with their primary partner (intervention 40.0%, SOC 36.7%) and with other sex partners (intervention 11.3%, SOC 8.8%). Almost two-thirds of participants reported having a sexual agreement with their partner (64%). Among those with an agreement ( $n = 101$ ), 41 (41%) reported monogamy, 13 (13%) reported an open relationship with no restrictions, and 47 (47%) reported an open agreement with some restrictions. The RCT began enrollment in 2014 when PrEP was emerging as a biomedical HIV prevention option: only 4% of negative partners reported currently taking PrEP.

In terms of indicators of engagement in HIV clinical care, at baseline the majority of men reported a clinical visit with a viral load test in the last six months (intervention 87.8%, SOC 90.3%), and reported that they were prescribed and taking ART (intervention 84.5%, SOC 87.8%). Approximately one-third of men reported missing at least one dose of ART in the past 30 days (intervention 38.1%, SOC 33.8%). Among those who reported at baseline that they had missed ART doses in the past 30 days, 48% reported missing one dose, 26% reported missing two doses and 26% reported missing more than three doses. At baseline, 63.4% of men in the intervention arm and 66.2% of men in the SOC had a laboratory confirmed viral suppression status.

Table 2 shows the temporal patterns in the indicators of engagement in HIV care. In general, engagement in HIV clinical care remained high throughout the RCT. The percentage of men reporting a clinical visit in the past 6 months with a viral load test was over 84% at each assessment point in each arm. Similarly, the percentages of those reporting being prescribed and taking ART was also high in both arms—over 73% at all assessment points—although differences in this indicator emerged between the SOC and intervention groups at 12 months (intervention 95.2%, SOC 79.7%) and 18 (intervention 96.9%, SOC 80.8%). Greater variation was seen in the percentage reporting missing a dose of ART in the past 30 days. While this was approximately one-third of all participants at baseline, by 12 months (intervention 17.5%, SOC 30.3%) and 18 months (intervention 10.3%, SOC 37.3%) reporting of missing ART dose was higher in the SOC group. The percentage of men who were laboratory confirmed as virally suppressed remained stable throughout the RCT.

Table 3 shows results of the modeling of the three primary engagement in HIV care outcomes and one exploratory outcome (viral suppression). There was no significant difference between men in the intervention and SOC arm in the self-report of attending a HIV clinical care visit in the past 6 months over time. Participants randomized to the intervention arm had a significantly greater odds of being prescribed and currently taking ART over time than those in the SOC arm (at 12 months OR 2.75, 95%CI 1.35–4.67,  $p$ -value 0.020, and at 18 months OR 2.91, 95%CI 1.61–4.88,  $p$ -value 0.013). Similarly, those in the intervention arm had a significantly lower odds of missing a dose of ART in the past

30 days over time compared to those in the SOC arm (at 12 months OR 0.28, 95% CI 0.09–0.81, p-value 0.019, and at 18 months OR 0.25, 95% CI 0.07–0.82, p-value 0.023). For our exploratory outcome—viral load suppression—there was no statistically significant difference between the two treatment conditions; however, the direction of effect trended towards an effect of the intervention (at 12 months OR 1.26, at 18 months OR 1.12).

While this paper reports on HIV clinical care engagement outcomes for the HIV positive male partners, it should be noted that there were 3 (2%) seroconversions detected among the HIV negative partners over the 18-month follow-up period: two seroconversions were in the intervention arm and one seroconversion was in the SOC arm; this was not significantly different by treatment condition ( $p > 0.5$ ). Each of these was linked to care within seven days of the preliminary positive test, and these seroconcordant couples were censored from additional study follow up visits.

## Discussion

Dyadic interventions provide an opportunity for male serodiscordant couples to learn the skills necessary to work together to manage HIV prevention and care in their relationship. In the current SOC, members of serodiscordant couples are seen separately. The HIV positive member receives individual clinical care, while the HIV negative member engages in HIV testing. While some providers may allow both members of the dyad to attend these visits together, there are currently no interventions treating the couple as a dyad and attempting to intervene at the dyadic level through the provision of shared skill building. *Stronger Together* builds off CHTC, a previously successful dyadic intervention that focused on allowing couples to learn their serostatus together and build joint prevention plans [54–56]. *Stronger Together* extended CHTC through the continuum of care allowing male couples to develop the skills necessary to support active and successful engagement in HIV care. The addition of Partner Steps—developed as a dyadic intervention from the efficacious LifeSteps intervention [50]—focused on giving couples the space and opportunity to talk about issues around ART adherence, and to work together with a counselor to develop a plan to encourage and sustain adherence. Importantly, these plans included actions for both members of the couple to be involved in, for example, setting reminders or providing emotional support.

Previous literature has demonstrated the importance of support in enabling adherence to ART [45–47]. The results of the *Stronger Together* intervention demonstrate the potential for an intervention that allows male serodiscordant couples to create concrete plans for supporting each other. During the CHTC and Partner Steps sessions, motivational interviewing techniques were used to enable couples to reflect on their current relationship and behaviors, to identify risks (to transmission and lapses in adherence) and to discuss strategies for addressing the risks. Important to the success of *Stronger Together* is the concept of a shared vision: a plan for engaging in HIV prevention and care that both members of the couple agree to. The results demonstrate a significant effect of the intervention on two key outcomes: being prescribed and taking ART and self-reported adherence to ART. The steps discussed in Partner Steps focused on the importance of ART and on sustained adherence, asking couples to develop practical solutions to problems they

identified. Interestingly, impacts on ART uptake and adherence were not seen until 12 months after intervention, perhaps suggesting that it takes time for couples to work through their prevention and care strategies and to arrive at actions that work for their relationship. However, results were sustained at 18 months, suggesting that once couples develop these skills, they can be maintained.

With respect to our exploratory outcome examining differences in viral load suppression between treatment arms, it is important to note that this study was not powered to determine this effect. If we were going the power the trial on viral load suppression, we would have likely enrolled couples for which the positive partner was not virally suppressed. As expected, there was no effect of the intervention on laboratory confirmed viral suppression, despite noted gains in ART uptake and adherence. This is likely because there was not a lot of variability for couples to improve on this outcome over time (i.e., many couples were already virally suppressed at baseline). However, the direction of effect (although not statistically significant) for viral suppression was suggestive of trend towards impact of the intervention and was close to significance at the 12 and 18 month assessment points. Further research with larger sample sizes is warranted to identify intervention effects on and pathways to viral suppression. Additionally, a larger sample size would permit stratified analysis to identify effects by relationship characteristics (e.g. sexual agreement type) and to explore the moderating effects of demographic (e.g. race) and behavioral (e.g., substance use) factors.

This sample of serodiscordant couples reported high levels of risk behaviors for HIV transmission and disengagement in HIV care, with high levels of substance use and binge drinking. 40% of couples reported CAI in their relationship, with very low levels of PrEP use (less than 5%). In particular, the prevalence of open sexual agreements was high, highlighting that the negative partner may still be at risk for HIV from sex outside of their primary relationship. Stronger Together allows couples to discuss these risks together, and to build prevention plans that they agree can work for the realities of their relationship. This risk profile justifies further programmatic and research attention towards developing interventions that can provide serodiscordant couples the information, skills and opportunities to work together on HIV prevention and care. Talking about sex—particularly risks around sex—can be challenging for many couples, and interventions such as *Stronger Together* provide a space for couples to work with a trained lay counselor to develop plans.

There are several limitations to the current RCT. The RCT screened out those who reported a recent history of IPV, to prevent the dyadic intervention triggering further violence. There is evidence that exposure to CHTC does not lead to incident IPV [56, 57]. It may be that couples who are experiencing IPV in their relationships may benefit from exposure to an intervention that creates communication skills and encourages joint planning, but further attention is needed to understand the prevention and care planning needs of couples experiencing IPV. In total, 27 couples dissolved during the RCT (although most of the positive partners were retained), and it is possible that factors that influenced the dissolution may also shape engagement in HIV care (for example, loss of medical insurance). Retention at 18 months was relatively high at 77%, but it is possible that those lost to follow up may have had differential care outcomes. Measurement of adherence relied on self-report, using

the Visual Analog Scale [52]. Although there is significant evidence of the validity of self-reported measures of ART adherence [58] it is possible that participants may have over-reported their adherence—which we would expect to be similar across the two arms—although the direction of effect of the intervention for viral suppression suggests accuracy of self-reported ART adherence. Further work is also warranted to measure how participation in Stronger Together shapes engagement in prevention behaviors (i.e. HIV testing and PrEP uptake) among negative members of serodiscordant dyads. The sample of couples was largely White and highly educated, and while the results illustrate that populations typically considered at lower risk of falling out of care or not taking ARV still have challenges with these critical behaviors, for *Stronger Together* to be fully scalable, it would need to be tested with a more diverse sample of sero-discordant couples.

## Conclusion

The *Stronger Together* intervention has the potential to fill a critical gap in efficacious interventions for male serodiscordant couples who, despite evidence of high rates of transmission within partnerships, have been largely ignored by HIV research and programming. The intervention utilizes lay counselors, similar to those who provide CTR, and thus has potential for scalability in community-based organizations that already provide HIV testing. However, the intervention is relatively intensive, with three in-person sessions, and further work is needed to explore whether the sessions can be provided via telehealth or some of the content provide via eHealth platforms. With promising results for effects on ART uptake and adherence, further work is needed to understand the pathways through which *Stronger Together* creates HIV prevention and care behavioral changes in serodiscordant male couples.

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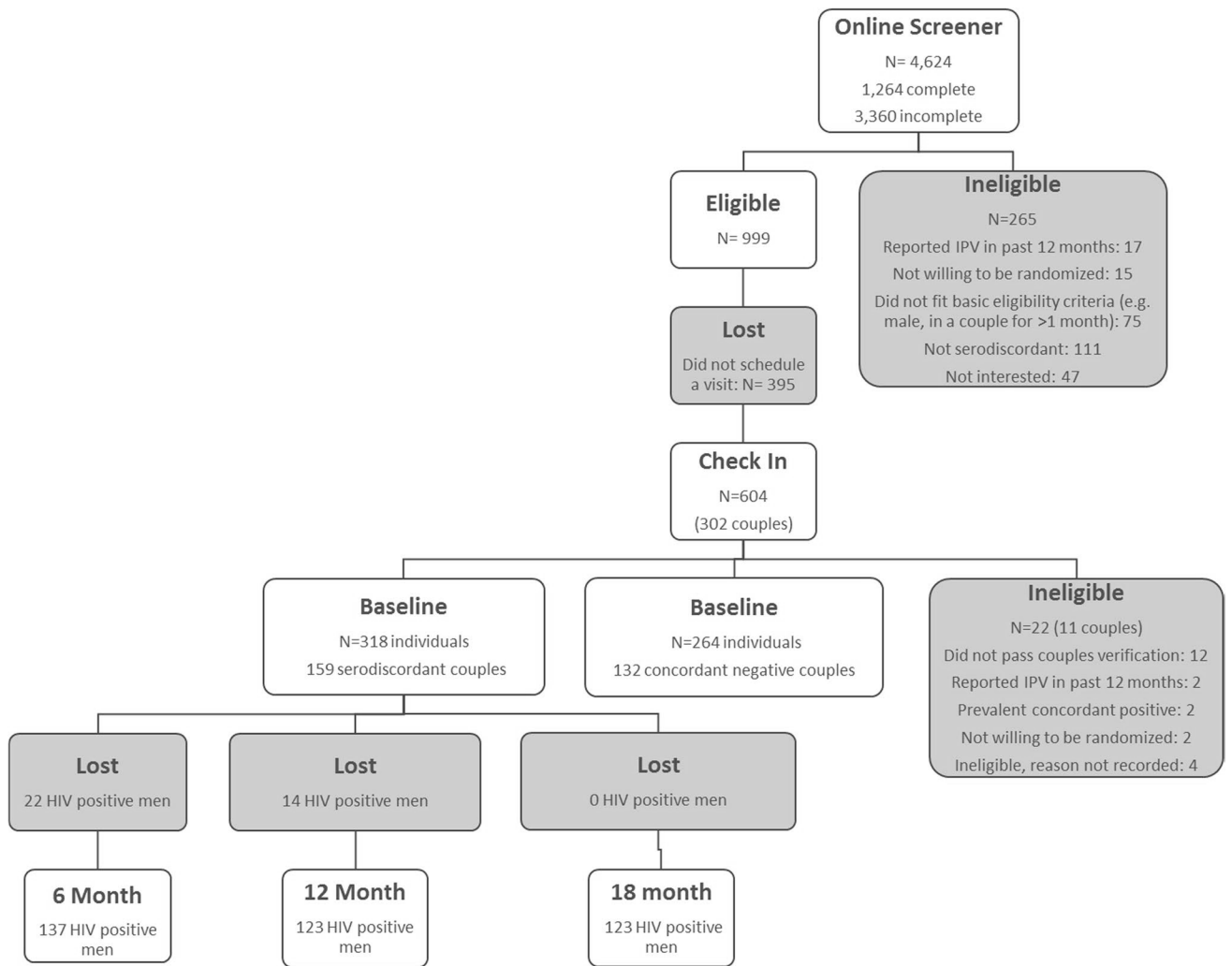
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**Fig. 1.** Consort diagram for RCT of *Stronger Together* Intervention

Baseline demographic, behavioral risk and engagement in HIV care variables for HIV-positive men with HIV-negative male partners (n = 159) in Atlanta, Chicago and Boston, 2014–2017

**Table 1**

	Intervention (n = 80)	Control (n = 79)	P-value
Mean age (years)	40.29 (21–69)	39.14 (18–67)	0.564
Hispanic ethnicity identity	6 (7.5)	7 (8.8)	0.235
White racial identity	55 (68.7)	50 (63.2)	0.691
Identifies as gay/homosexual	75 (93.4)	70 (88.6)	0.251
Has been arrested in past 12 months	29 (36.2)	34 (43.0)	0.256
Spent time in jail in past 12 months	13 (16.2)	17 (21.5)	0.431
Currently employed (fulltime/part time)	63 (78.8)	69 (87.3)	0.132
Currently cohabiting with partner	53 (66.2)	60 (75.9)	0.157
Married to male partner	14 (17.5)	13 (16.4)	0.762
Reports non-prescription substance use in past 6 months	19 (23.8)	18 (22.8)	0.984
Reports binge drinking alcohol in past 6 months	38 (47.5)	37 (46.8)	0.973
Mean score for depressive symptomology	8.13 (0–18)	8.76 (0.18)	0.896
Sexual behavior			
Has UAI with main partner	32 (40.0)	29 (36.7)	0.646
Has UAI with main partner and other partners	9 (11.3)	7 (8.8)	
Have a sexual agreement with their partner	51 (63.4)	50 (62.8)	0.564
Has attended clinical appointment for HIV care with a viral load test in past 6 months	70 (87.8)	71 (90.3)	0.466
Currently prescribed and taking ART	67 (84.5)	69 (87.8)	0.651
Has missed more than one ART dose in past 30 days	30 (38.1)	27 (33.8)	0.415
Laboratory confirmed virally suppressed	51 (64.3)	52 (66.2)	0.801

**Table 2**

Engagement in HIV care indicators for HIV-positive men with HIV-negative male partners, by experimental group and time among 159 male couples in Atlanta, Chicago and Boston, 2014–2017

	Baseline (n = 159)		6 months (n = 127)		12 months (n = 123)		18 months (n = 123)	
	Control n = 79	Intervention n = 80	Control n = 63	Intervention n = 64	Control n = 61	Intervention n = 62	Control n = 61	Intervention n = 62
% attended clinical appointment for HIV care with a viral load test in past 6 months (n)	90.3 (71)	87.8 (70)	95.3 (60)	94.3 (60)	92.9 (57)	96.8 (60)	84.3 (51)	91.7 (57)
% currently prescribed and taking ART (n)	87.8 (69)	84.5 (67)	81.8 (52)	73.2 (47)	79.7 (49)	95.2 (59)	80.8 (49)	96.9 (60)
% who missed more than one ART dose in past 30 days (n)	33.8 (27)	38.1 (30)	34.9 (22)	39.4 (25)	30.3 (18)	17.5 (10)	37.3 (23)	10.3 (6)
% Laboratory confirmed virally suppressed (n)	66.2 (52)	64.3 (51)	75.5 (48)	69.0 (44)	63.3 (39)	74.6 (46)	65.5 (40)	78.1 (48)

Table 3

Adjusted odds ratios, 95% confidence intervals and P-values for associations between exposure to *Stronger Together* intervention and engagement in HIV care outcomes among 159 male couples in Atlanta, Chicago and Boston, 2014–2017

Study Arm	Has attended clinical appointment for HIV care with a viral load test in past 6 months OR, 95%CI, P-value	Currently prescribed and taking ART OR, 95%CI, P-value	Has missed more than one ART dose in past 30 days OR, 95%CI, P-value	Laboratory confirmed virally suppressed OR, 95%CI, P-value
Control	1.00	1.00	1.00	1.00
Intervention	0.77, 0.27–2.15, 0.626	0.75, 0.30–1.88 0.549	1.20, 0.62–2.31, 0.574	0.91, 0.47–1.77, 0.799
Time				
Baseline	1.00	1.00	1.00	1.00
6 months	2.15, 0.53–8.71, 0.282	0.62, 0.24–1.58, 0.549	1.04, 0.52–2.10, 0.895	1.54, 0.75–3.34, 0.799
12 Months	1.40, 0.38–5.04, 0.607	0.54, 0.21–1.58, 0.203	1.21, 0.59–2.47, 0.585	0.88, 0.43–1.79, 0.782
18 Months	0.57, 0.19–1.71, 0.323	0.58, 0.21–1.55, 0.279	0.73, 0.34–1.57, 0.430	0.96, 0.46–2.01, 0.925
Arm * Time				
Arm * 6 months	1.06, 0.16–6.74, 0.948	0.80, 0.23–2.74, 0.728	1.00, 0.39–2.61, 0.985	0.77, 0.28–2.11, 0.620
Arm * 12 months	3.02, 0.40–2.27, 0.282	<b>2.75, 1.35–4.67, 0.020</b>	<b>0.28, 0.09–0.81, 0.019</b>	1.26, 0.46–3.39, 0.061
Arm * 18 month	2.63, 0.55–12.63, 0.225	<b>2.91, 1.61–4.88, 0.013</b>	<b>0.25, 0.07–0.82, 0.023</b>	1.12, 0.41–3.04, 0.083

Bold values are significant at 5% level