Evidence for use of a healthy relationships assessment tool in the CHARISMA pilot study

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Abstract

Introduction

The CHARISMA intervention, nested within the MTN-025/HOPE vaginal ring trial in Johannesburg, South Africa, seeks to facilitate women’s use of HIV prevention products by promoting partner dialogue and mitigating intimate partner violence (IPV). We developed “HEART”, a lay counselor-administered relationship assessment tool, for the CHARISMA pilot. The five-scale tool assesses participants’ endorsement of Traditional Values (TV), her HIV Prevention Readiness (HPR) and levels of partner support (PS), abuse and control (PAC), and resistance to HIV prevention (PR), guiding decisions about which of three counselling modules to offer (partner communication/A; ring disclosure/B; and IPV prevention/C).

Methods

We correlated baseline scores on HEART subscales with a) independent measures of relationship stability, disclosure and IPV to assess construct validity, and b) with specific modules offered to determine how HEART was used in the pilot. We examined changes in HEART scores at three and six months. Finally, we ran separate growth models for each subscale to examine changes in scores, accounting for partnership changes and counseling module(s) received.

Results

Baseline HEART scores correlated as predicted among subscales and with other measures. Reliabilities for four subscales were 0.75 or higher. Women who disclosed study participation and ring use scored higher on PS and lower on PR. Women experiencing IPV scored lower on PS, and higher on PAC and PR. During the pilot, 82% of women received one and 17% received two or more modules; over half received the IPV module. Women with higher PAC and PR scores were more likely to receive the IPV than the communication...
or disclosure modules. Over time, the TV, PAC and PR scores decreased, and PS score increased. Receiving the IPV module was associated with a decreased PAC score.

Conclusions
These data offer preliminary evidence for HEART construct and predictive validity and support its further evaluation to guide implementation and monitor the impact of the CHARISMA intervention in a randomized controlled evaluation.

Introduction
Women worldwide continue to be at risk of HIV, with younger southern African women often at highest risk [1]. Women’s sources of risk are multiple, but often intertwined with the dynamics of their social and sexual relationships. In one cohort study of more than 1000 women in Cape Town, SA, women who experienced intimate partner violence (IPV) were 1.5 times more likely to acquire HIV, and women with lower levels of relationship power had higher rates of HIV infection than those with higher power [2]. In several trials evaluating new vaginal and oral pre-exposure prophylaxis (PrEP) HIV prevention products within these same populations, adherence has been low [3–6]. Low adherence in clinical trial settings has been attributed to concerns about using experimental products [7, 8]; alternative (non-product) motivations for trial participation, low perceived risk of HIV [9], and social and sexual challenges related to trial and product use [10, 11]. Such challenges reportedly include overcoming male partners’ distrust of trial objectives, their concerns about potential product-related side effects or about how product use and trial participation might disrupt existing relationship dynamics, including by facilitating a female partner’s promiscuity or encouraging greater female autonomy [12].

In demonstration studies in which product efficacy is known, adolescent girls and young women (AGYW) have shown interest in using oral PrEP. However, in several studies initial uptake remained low, and among those who initiated PrEP, adherence to and persistence of PrEP decreased over time [13–17]. For example, among more than 1200 HIV-uninfected Kenyan women who were screened for PrEP in the context of family planning services, 278 women initiated PrEP and fewer than half (114, or 41%) returned for at least one refill. Continuation at six months was 15% [16]. In qualitative interviews with Kenyan AGYW accessing PrEP through maternal child health and family planning clinics, negative reactions from male partners were frequently raised as a reason for non-use or discontinuation of PrEP [18]. In an oral PrEP demonstration study with serodiscordant couples, women reporting recent IPV were more likely to have low adherence [19, 20]. These studies suggest that the need to negotiate PrEP use and the potential for a partner’s lack of support, his resistance or active abuse remain barriers to women’s use of new prevention methods, even when discreet use is theoretically possible. To date, few interventions have been developed or evaluated that directly support women’s ability to engage (or not engage) their partners in the context of clinical trial participation or routine use of PrEP.

Addressing this gap, the Community Health clinic model for Agency in Relationships and Safer Microbicide Adherence (CHARISMA) intervention was developed to increase women’s agency to consistently and safely use ARV-based HIV prevention products such as vaginal microbicides and oral pre-exposure prophylaxis (PrEP), while also reducing their risk of intimate partner violence (IPV) and promoting healthy relationships [21]. CHARISMA was pilot...
tested at the Wits Reproductive Health and HIV Institute (Wits RHI) site in Johannesburg, South Africa. Women who had previously participated in the Phase 3 MTN-020/ ASPIRE trial (ClinicalTrials.gov number NCT01617096 and NCT02858037), evaluating the safety, acceptability and effectiveness of a monthly vaginal ring (VR) containing 25 mg of dapivirine and had then transitioned to the MTN-025/HIV Open-label Prevention Extension (HOPE) trial, which assessed the extended safety of and adherence to VR use were eligible to enroll. Women who agreed to participate in the six-month CHARISMA pilot intervention study received differentiated in-person counseling based on a baseline assessment of their primary relationship using the HEAlthy Relationship Assessment Tool–referred to as HEART; both HEART and the differentiated counseling module were delivered by a trained lay counselor. Counseling modules included: partner communication (A), ring disclosure (B) and IPV prevention (C).

The initial development and validation of HEART, which was conducted prior to CHARISMA pilot study implementation, has been described elsewhere [21, 22]. The purpose of this manuscript is to describe the performance and prospective validity of HEART, from which we can infer the tool’s utility to screen, monitor and/or intervene on women’s relationships within the context of PrEP delivery. In this manuscript, we use initial scale development data collected during formative work and data from the pilot intervention to examine how the pilot HEART subscales: 1) perform vis-à-vis the initial scale development survey, 2) correlate with other baseline measures describing pilot participants’ relationships, 3) were used to guide the counseling component of the intervention, and 4) performed over time. The results of these analyses informed the use of the HEART tool in a final randomized controlled effectiveness evaluation of the CHARISMA intervention (manuscripts forthcoming.)

Methods

Parent studies

Our analyses draw on two separate studies. In our formative study, conducted between April to September 2016 at Wits RHI, we administered a cross-sectional survey, consisting of 127 potential HEART items and relevant socio-demographic and risk behavior variables, to 309 women. Eligible women were aged 18 to 40, and either had prior experience as former trial participants (FTPs) in HIV prevention research or were trial-naïve participants (TNPs). While more fully described in a separate manuscript [22], the goal of the formative study was to identify constructs (e.g., partner support, abuse or other dimensions of partner relationships) and items (e.g., the specific questions or statements) that could characterize women’s primary relationships and be formalized in a counselor-administered tool to guide various modules offered as part of the CHARISMA intervention. As described in an earlier paper [21], potential items for the tool were drawn from existing index or scale measures of IPV [23–25], sexual power–including the Sexual Relationship Power Scale [26, 27], or partner support and decision-making [28]. Because many of the original measures comprised 10–40 items each, we conducted an exploratory scale development process to determine whether an abbreviated set of items, feasible for use in a clinic setting, might emerge that assessed the spectrum of partner dynamics, from supportive to abusive.

The pilot CHARISMA intervention was conducted from December 2016 to October 2018. Also described elsewhere [29], this intervention co-enrolled all 95 women at the Wits RHI site who were current participants in the HOPE open-label extension of the dapivirine vaginal ring. (An additional five participants enrolled in HOPE after the CHARISMA enrollment period had ended, so did not participate in the pilot). All participants in the pilot CHARISMA intervention were administered the HEART at baseline and then received a brief module on healthy relationships, which included counseling on forms of abuse and control. Depending
on their HEART scores and information about whether they had disclosed study participation and/or product use to a partner, they also might have received a module on a) partner communication; b) ring disclosure; or c) IPV prevention. All women were also offered referrals to external services. A brief booster counseling session was provided to participants at month 1, or at three- and six-month visits if new partners or IPV were reported during follow-up. However, the HEART was administered at month 1 only to those participants who reported having a new partner. At months three and six the HEART was administered to all participants to measure any changes in attitudes or relationship behaviors, but not to guide delivery of additional counseling.

The participants enrolled in both the formative and pilot studies were recruited through the Wits RHI site in Johannesburg, South Africa. Both studies were reviewed and approved by the University of Witwatersrand Human research ethics committee (HREC). In addition, the formative study was reviewed and approved by FHI 360’s Protection of Human Subjects Committee. The RTI IRB deferred approval decisions to the HREC IRB for the pilot CHARISMA intervention. Participants in both studies provided written informed consent prior to enrollment.

**Measures**

The HEART comprises five subscales and a total of 42 statements. All items are scored on a 6-point scale from strongly disagree (coded 1) to strongly agree (coded 6). The subscales were:

1. Traditional Values (TV): 13 items describing norms valuing masculinity (e.g., A man should have the final say in all family matters; I think there is nothing a woman can do if her husband wants to have girlfriends);

2. Partner Support (PS): 10 items describing ways that the relationship with her partner is/is not supportive or harmonious (e.g., My partner is as committed as I am to our relationship/My partner does what he wants, even if I do not want him to);

3. Partner Abuse & Control (PAC): 9 items describing a partner’s psychologically or physically abusive behaviors or their outcomes (e.g., My partner makes fun of me or humiliates me; My partner slaps, hits, kicks, or pushes me; I can’t seem to make good decisions about my life);

4. Partner Resistance to HIV Prevention (PR): 5 items describing partner’s unwillingness to talk about or use HIV prevention (e.g., If I asked my partner to use a condom, he would get angry); and

5. HIV Prevention Readiness (HPR): 5 items expressing individual or joint readiness to use HIV prevention products (e.g., Using an HIV prevention product shows that my partner and I care about each other).

In both studies, the HEART items were electronically administered by a researcher or counselor on a tablet. In the CHARISMA pilot, item responses within each subscale were summed to obtain a subscale score after replacing any missing item response by the mean of the available responses. The participants’ subscale scores were compared to the mean scores from the original formative study. Scores in the pilot CHARISMA intervention that were one or more standard deviations below the formative study mean (the benchmark) were determined to be “low” in terms of the construct, while those that were one or more standard deviations above the mean were determined to be “high”. All other scores fell into a “medium” category. The HEART tool produced a report noting which, if any, subscales were in the “risk zone”. For example, a PS summary score that was one or more standard deviations below the benchmark,
or a PAC or PR score that was one or more standard deviations above the benchmark from the formative study, was considered a risk and flagged by the report, recommending that the counselor offer the IPV module to the participant. (The IPV module could also be offered at the discretion of the counselor, regardless of HEART score on these subscales. Counselors typically offered the IPV module for women in the moderate and high-risk categories.)

**Other variables: Relationship stability.** At baseline, participants were asked whether they had a primary partner in the last three months and, if so, whether this was the same partner they had during their previous trial participation, as well as whether they were living with their primary partner. **Disclosure.** At each visit, participants were asked whether their primary sex partner knew about their use a vaginal ring as part of this study. Response options were “Yes”, “No”, and “Not sure”. **IPV.** At each visit, women were asked a four-part question about whether their primary sex partner or any other current or previous partner had ever committed acts of physical or sexual violence against them within the past 3 months and was classified as experiencing IPV if a response of “yes” was given to any part of the question.

**Analytic approach**

In this analysis, we used the CHARISMA pilot intervention data to prospectively validate the HEART. We compared the subscale mean scores, reliabilities and correlations to those from the original formative survey to assess whether the tool performed similarly in different samples (RQ1). We assessed construct validity by correlating the pilot study baseline scores on the HEART subscales with a) independent measures of relationship stability, disclosure and IPV to assess construct validity (RQ2), and b) specific modules offered to determine how HEART was used in the pilot (RQ3). We also fit simple and multivariable logistic regression models to further assess the strength of the associations between the HEART subscales and reports of IPV and disclosure of ring and study to partner. Finally, to examine the predictive validity of the tool, we examined changes in HEART scores at three and six months (follow-ups 1 and 2) and ran separate growth models for each subscale to describe changes in scores, accounting for changes in partner relationship and receipt of counseling modules (RQ4).

**Results**

Women in the formative study included both trial-naı̈ve participants (TNP) and those with former trial experience (FTP). As presented in Table 1, trial-naı̈ve participants tended to be younger, less likely to have children or to earn their own income than those who had formerly or were currently participating in a clinical trial. Women participating in the CHARISMA pilot study were older than participants in the earlier formative study, but more similar in age, education status, having children and earning an income, to FTPs than to TNP from the formative study.

The results of our HEART validations are presented below, organized by four core research questions, that examine how the pilot HEART subscales: 1) perform vis-à-vis the initial scale development survey, 2) correlate with other baseline measures describing pilot participants’ relationships, 3) were used to guide the CHARISMA intervention, and 4) performed over time in the CHARISMA pilot intervention.

**Research question 1: How do pilot HEART subscales perform vis-à-vis the formative scale development survey?**

Fig 1 presents a side-by-side visual representation of subscale correlations between the formative and pilot study samples, with positive correlations represented in blue and negative correlations in red, and with larger circles and deeper shades of color representing stronger
First, correlations between the different subscales in the pilot study were similar in direction and strength to what we had predicted and found in the original formative survey. As shown in Fig 1, the PAC scale was strong and inversely correlated with PS (-0.64 in the formative survey and -0.63 in the pilot study) and strongly positively correlated with PR scores (0.53 and 0.52 respectively). The TV subscale showed a similar direction and level of correlation with PS in both studies, but the strength of positive correlations was stronger in the formative survey than in the pilot. In contrast, inverse relationships between HPR and several subscales (PAC and PR) were stronger in the pilot study.

Additionally, the subscale reliabilities in our pilot study were similar to those in the original survey (Table 2). The Cronbach Alpha coefficient, which measures how closely related individual items are to the subscale construct, was equal to or greater than 0.70 in the same four HEART subscales for both samples, demonstrating generally acceptable levels of internal

Table 1. Sociodemographic characteristics of formative and pilot study samples.

|                        | Formative Survey | Pilot |
|------------------------|------------------|-------|
|                        | ALL (n = 309)    | TNP (n = 245) | FTP (n = 64) | FTP (n = 96) |
| Mean age in years, (range) | 27 (18–46) | 26 (18–46) | 29 (19–46) | 31 (21–48) |
| Proportion of participants aged ≤ 25 | % | % | % | % |
| Ever participated in HIV prevention clinical trial research | 21 | n/a | 100 | 100 |
| Type of trial: | n/a | n/a | 88 | 100 |
| Vaginal ring | | | 8 | |
| Vaginal gel | | | 5 | |
| Other (not oral PrEP) | | | 8 | |
| Have children | 68 | 66 | 77 | 82 |
| Highest level of education: | | | |
| Incomplete secondary, or less | 28 | 28 | 24 | 30 |
| Secondary, complete | 37 | 34 | 48 | 46 |
| Attended college or university | 36 | 39 | 28 | 24 |
| Earns an income | 36 | 32 | 52 | 44 |

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reliability [30]. One exception, however, was the HPR reliability measure, which was borderline in the formative survey and even lower in the pilot study. (S1 table provides additional measures of reliability for two samples.)

Research question 2: How do HEART subscales correlate with other baseline measures describing pilot participants’ relationships?

In our formative study analysis [22], we predicted and confirmed that PAC and PR scales would be positively correlated with measures of IPV and negatively associated with disclosure. Similarly, we found that PS was negatively correlated with IPV measures, but positively correlated with disclosure. However, HEART associations with sociodemographic and relationship variables were less likely to match our predictions.

Among the pilot population, we found similar patterns of association. As shown in Table 3, women who reported any IPV had lower PS scores (e.g. 43.9 vs 49.6) and higher PAC and PR scores than women who did not report any IPV (e.g., 21.9 vs 14.4; 13.2 vs.7.9 respectively), with differences all large enough to be statistically significant (at the value \(p < 0.1; \quad ** \times p < 0.05; \quad *** \times \times \times p < 0.01\)). Although women who reported any IPV also had higher TV scores, the difference was not statistically significant in this sample. With regards to disclosure, women who fully disclosed ring use and study participation to their partners had higher PS and lower PR scores, with marginally significant differences in mean scores (at \(p < 0.1\)).

Younger women aged 18 to 25 scored higher on the PAC subscale than older women (\(p = .05\)). Women who reported living with a partner scored significantly higher in PAC and PR. All the differences in PS, PAC, PR and HPR are in the originally hypothesized direction, though the differences in some cases were not as large as expected.

To further explore the nature and strength of the relationships between the HEART scores and the three partner-related indicators (i.e., experiencing any IPV, full disclosure, and living with a partner), we fit a series of logistic regression models using the indicator as the outcome and the scaled versions of the HEART scales as predictors (Table 4). We found that after controlling for all the HEART scores, a one-standard deviation in the PAC score was associated with a 11% increase in the odds of experiencing any form of IPV. Also, a one-standard deviation in the PR score is associated with 14.5% higher odds of experiencing IPV and 10% lower odds of full disclosure to their partners.

Research question 3: How have HEART subscales been used to guide the CHARISMA pilot intervention?

During the CHARISMA pilot, counselors relied on both the HEART subscale scores, women’s reported disclosure to partners, and their own discretion to determine which intervention module(s) to offer. Most women (82%) received one module and 17% received two or more modules; over half of participants were offered and received the IPV module (Table 5).
All but one woman who reported IPV at baseline were offered the IPV module based on their HEART scores. (The counselor overrode the IPV recommendation because this participant recently changed partners and was now in a more supportive relationship.) Additionally, almost half of women who did not report IPV were also offered this module. As would be expected, these women had significantly higher PAC and PR scores, and lower PS scores, than other women who did not report IPV and were assigned the communication or disclosure module.

Table 3. Comparison of HEART mean scores by independent partner measures.

|                          | Any IPV | Diff. (SE) | Full Disclosure | Diff. (SE) |
|--------------------------|---------|------------|-----------------|------------|
|                          | No N = 83 | Yes N = 12 |                |            |
| Traditional Values (TV)  |          |            |                |            |
| (range 13–78)            | 25.6     | 29.7       | −4.02 (3.46)    |            |
| Partner Support (PS)     | 49.6     | 43.9       | 5.72* (3.03)    |            |
| (range 10–60)            |          |            |                |            |
| Partner Abuse & Control (PAC) | 14.4   | 21.9       | −7.54*** (2.77) |            |
| (range 9–54)             |          |            |                |            |
| Partner Resistance (PR)  | 7.9      | 13.2       | −5.39** (2.56)  |            |
| (range 5–30)             |          |            |                |            |
| HIV Prevention Readiness (HPR) | 28.6   | 28.7       | −0.05 (0.62)    |            |

|                          | No N = 70 | Yes N = 25 | Diff. (SE) | No N = 36 | Yes N = 59 | Diff. (SE) |
|--------------------------|-----------|-----------|------------|-----------|-----------|------------|
| Aged ≤ 25 vs > 25        |           |           |            |           |           |            |
| Traditional Values (range 13–78) | 27.1     | 23.7      | 3.42 (2.9)  | 25.28     | 27.5      | −2.26 (2.68) |
| Partner Support (range 10–60) | 49.6     | 46.9      | 2.76 (2.21) | 49.1      | 48.6      | 0.48 (1.88) |
| Partner Abuse & Control (range 9–54) | 14.5   | 17.8      | −3.3* (1.68) | 14.2      | 17.1      | −2.92** (1.62) |
| Partner Resistance (range 5–30) | 8.3      | 9.1       | −0.74 (1.28) | 7.9       | 9.7       | −1.91* (1.14) |
| HIV Prevention Readiness (range 5–30) | 28.6     | 28.6      | 0.08 (0.59)  | 28.7      | 28.5      | 0.13 (0.57) |

* Associated probability value (p) < 0.1
** p < 0.05
***p < 0.01 from Student t-tests assuming unequal variances. One-sided hypothesis tests for all subscales except Traditional Values.

https://doi.org/10.1371/journal.pone.0261526.t003

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Table 4. Unadjusted and adjusted logistic regression models of HEART scores on (1) reports of any IPV and (2) disclosure of ring and study to partner.

|                          | Reported experiencing any IPV | Disclosure of ring and study to partner |
|--------------------------|-------------------------------|----------------------------------------|
|                          | Unadjusted OR (SE) | Adjusted OR (SE) | Unadjusted OR (SE) | Adjusted OR (SE) |
| Traditional Values (TV)  | 1.02 (0.02)               | 1.00 (0.03)               | 1.00 (0.02)               | 1.02 (0.02)               |
| Partner Support (PS)     | 0.95* (0.03)              | 1.02 (0.06)              | 1.05** (0.02)              | 1.06* (0.04)              |
| Partner Abuse & Control (PAC) | 1.12*** (0.04)       | 1.11* (0.07)         | 0.98 (0.03)               | 1.07 (0.05)               |
| Partner Resistance to HIV Prevention (PR) | 1.15*** (0.05)       | 1.14** (0.07)        | 0.91** (0.04)             | 0.90* (0.05)             |
| HIV Prevention Readiness (HPR) | 1.01 (0.13)            | 1.40 (0.34)            | 1.10 (0.09)               | 1.02 (0.1)               |

* Associated probability value (p) < 0.1
** p < 0.05
***p < 0.01.

https://doi.org/10.1371/journal.pone.0261526.t004
Research question 4: How do HEART subscales perform over time?

Over time, the model-predicted scores for PAC (Fig 2), TV and PR (S1 and S3 Figs) decreased and the PS score (S2 Fig) increased among all participants. Women who reported any IPV at baseline had larger increases over time in PS, as well as decreases in PAC and PR, than women who did not report IPV. Receiving IPV counseling was associated with a decrease from baseline to follow-up 1 at month 3 in the PAC score, regardless of whether IPV was reported at baseline. Between follow-ups, the decrease was associated mostly with having reported IPV at baseline.

Fig 2 below shows the model-predicted change in PAC scores for groups of women who did and did not report IPV at baseline and were or were not assigned the IPV module. Note that women who received the IPV module showed steep declines in PAC scores, with women who reported IPV at baseline and received this module showing the steepest declines from baseline to the month 6 endline. As expected, the PAC scores were lowest at baseline and remained low over time among women who reported no IPV at baseline and did not receive the IPV module.

Discussion

In this study, we evaluated the performance of a multi-dimensional tool called HEART to assess the quality of women’s primary relationship, including the level of partner support and

Table 5. Number and % of women assigned to counseling modules, over follow-up.

| Module          | Baseline N = 95 | 1st follow-up N = 91 | 2nd follow-up N = 77 |
|-----------------|-----------------|----------------------|----------------------|
| A: Partner communication | 27 (28.4) | 15 (16.5) | 8 (10.4) |
| B: Disclosure   | 31 (32.6) | 12 (13.2) | 12 (15.6) |
| C: IPV          | 55 (57.9) | 20 (22.0) | 10 (32.3) |

Table 6. Relationship between baseline HEART scores (PS, PAC and PR), baseline reports of IPV and receiving the IPV module.

| No IPV Reported at Baseline | IPV Reported at Baseline |
|-----------------------------|--------------------------|
| No IPV module | IPV module assigned | Difference | No IPV module | IPV module assigned | Difference |
| Baseline         | (n = 39)                  | (n = 44)                  | 3.20***       | (n = 1)                  | (n = 11)                  | 11.0       |
| PS              | 52.9                      | 46.7                      | 54             | 43.0                      | 10.0                      |
| PAC             | 10.4                      | 17.9                      | 15             | 22.5                      | 7.5                      |
| PR              | 6.4                       | 9.2                       | 5              | 14.0                      | 9.0                      |
| Follow-up #1    | (n = 66)                  | (n = 13)                  | -6.22***      | (n = 5)                  | (n = 7)                  | 7.5        |
| PS              | 54.7                      | 49.6                      | 48.4           | 40.6                      | 1.2                      |
| PAC             | 11.1                      | 14.1                      | 17.4           | 18.4                      | -0.2                     |
| PR              | 6.0                       | 6.3                       | 8.4            | 11.4                      | -0.7                     |
| Follow-up #2    | (n = 58)                  | (n = 7)                   | -2.96***      | (n = 9)                  | (n = 3)                  | 8.7        |
| PS              | 55.4                      | 48.4                      | 55.3           | 50.3                      | 1.1                      |
| PAC             | 10.3                      | 11.4                      | 11.3           | 13.3                      | 0.8                      |
| PR              | 5.9                       | 9.1                       | 5.1            | 8.7                       | -8.9***                  |

* Associated probability value * p < 0.1
** p < 0.05
***p < 0.01. No statistical tests were conducted among women who reported IPV at baseline since only one woman in this group was not assigned the IPV module.
the potential for conflict, to guide selection of counseling modules that might support PrEP use. Overall, the tool’s psychometric properties, including subscale intercorrelations and reliabilities, were similar in two different samples of South African women. In the pilot CHARISMA study, women reporting baseline IPV also had significantly higher scores on PAC and PR scales than women who did not report IPV at baseline. Women who had not fully disclosed to their partners about either/or both study participation and vaginal ring use had significantly lower PS and higher PR scores.

Although the HEART was not used exclusively to determine which counseling modules to offer women during the pilot CHARISMA intervention, those who received the IPV module reported significantly lower levels of PS and higher levels of PAC and PR than other women. This suggests that counselors were applying information from the HEART in a consistent way, even if recommending the IPV module more liberally than originally intended. Furthermore, the intermittent administration of HEART over the 6-month intervention facilitated prospective monitoring. Indeed, changes in HEART scores over time indicated improvements in relationship dynamics, with steep reductions in PAC scores for most women except those who had low baseline PAC scores, and the steepest declines among women who received the IPV module.

Despite some promising results, our study has several limitations. First, evidence of HEART validity has only been demonstrated among adult women recruited through a clinical trial setting in Johannesburg, SA. In the pilot intervention, almost all women had a primary sexual partner but less than 40% lived with their partner. It remains unclear how well the HEART tool will perform overall, or by individual subscale, among women in other geographic settings or among those who have different relationship contexts. Furthermore, while all but the HPR scale showed moderate to good psychometric properties across the two studies, only three of the five subscales provided partnership-related information that directly informed the intervention. In fact, the HPR scale continued to be strongly skewed, as identified in our first analysis [22]. Based on these results, we considered eliminating the HPR and...
TV scales from the tool prior to implementing the effectiveness study. However, interim evaluation of the pilot [31] suggested that the progress of constructs and items in the HEART evoked deeper, yet non-threatening reflection among participants of their relationship with a primary partner. This led us to revise and further study HEART constructs in the upcoming effectiveness study, rather than eliminate immediately. And, finally, the goal of the pilot CHARISMA intervention, of which HEART is a component, is to assist women to safely and effectively adhere to PrEP products. As yet, we are not able to evaluate whether HEART scores can prospectively identify women who face challenges adhering to PrEP use.

In a final expansion phase of the CHARISMA project, a randomized controlled trial aims to evaluate the effectiveness of the CHARISMA intervention in the context of oral PrEP provision. As part of this expansion study, we will address several remaining questions related to HEART. One question is whether it is possible to improve the HPR subscale [22] by revising subscale content or whether the subscale should be removed from HEART. From a feasibility perspective, a smaller tool with fewer items would take less time to implement in a busy clinic setting. In an interim assessment of CHARISMA acceptability and feasibility, most participants (61%) felt the tool took the right amount of time, while 25% felt it was too long [31]. On the other hand, some lay counselors noted that the flow of the tool, which moves from more normative items related to gender-based values to partner support, partner abuse and control, resistance towards HIV prevention and finally HIV prevention readiness facilitated participants’ ability to think carefully about their current relationship. A shorter and more focused tool might be experienced as too abrupt and not reflective of participants’ nuanced relationships. Another linger question is whether to narrow the range of scores that would lead to a decision to offer the IPV module. The goal is to ensure that the tool is both sensitive to identifying women who could face partner-related challenges to adherence, but also targeted to those who will benefit from IPV or disclosure modules without distressing clients or overburdening counselors. During the interim assessment, some women felt that they had been incorrectly identified as being at high-risk for IPV and objected to receiving the IPV module [31].

There are several ethical issues with using a tool to guide clinical decisions related to IPV counseling. First, it is likely preferable to offer IPV counseling and resources to women who do not need it rather than miss offering them to women who might not be comfortable reporting it. However, such counseling can be very resource and time-intensive, particularly if the content does not address a recipient’s life context. A second issue relates to measurement. Given the stigma of directly disclosing IPV [32, 33], we designed a tool that used a less direct route to identify potential IPV. Indeed, the multi-dimensional HEART tool successively orients women to think through their relationship by moving through a series of statements related to traditional values and partner support before moving into items related to partner control and abuse. Additionally, the ability to indicate a level of agreement rather than a binary “yes or no” outcome may also make it easier to form women to acknowledge relationship concerns. Second, in the pilot we applied a fairly broad range of PAC scores to module C offering. Informal feedback from pilot intervention counselors indicated that some women whose scores suggested they receive the IPV module strongly disagreed with that assessment, leading us to conclude that over-prescribing the IPV intervention may also have its ethical challenges. An important take-home from the pilot study was the importance of using such decision-tools flexibly with final decisions about which module to offer remaining with the counselor or clinician.

In the Effectiveness Study, we will determine the degree to which the HEART and/or specific subscales help intervene to support partner communication, disclosure and negotiation of PrEP and ultimately lead to better adherence.
Conclusions
These data offer preliminary evidence for HEART construct and predictive validity and support its further evaluation to guide implementation and monitor the impact of the CHA-RISMA intervention in the randomized controlled study.

Supporting information
S1 Table. Various measures of reliability for survey and pilot samples. Raw Alpha: Cronbach Alpha (based upon the covariances); Std Alpha: Standardized Alpha (based upon the correlations); G6: Guttman’s Lambda 6 reliability.

S1 Fig. Model-predicted traditional values score by baseline IPV status and whether they received the IPV counseling module.

S2 Fig. Model-predicted partner support score by baseline IPV status and whether they received the IPV counseling module.

S3 Fig. Model-predicted partner resistance score by baseline IPV status and whether they received the IPV counseling module.

Acknowledgments
We would like to acknowledge the willing contributions of the women who participated in this study without whom this study would not have been possible. The contributions of the CHA-RISMA study team and community stakeholders are acknowledged as critical in the implementation of this study.

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References

1. Karim SA, Baxter C, Frohlich J, Karim QA. The need for multipurpose prevention technologies in sub-Saharan Africa. BJOG. 2014; 121 Suppl 5:27–34. https://doi.org/10.1111/1471-0528.12842 PMID: 25335838

2. Jewkes RK, 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. Lancet. 2010; 376(9734):41–8. https://doi.org/10.1016/S0140-6736(10)60548-X PMID: 20557928

3. Baeten JM, Palanee-Phillips T, Brown ER, Schwartz K, Soto-Torres LE, Govender V, et al. Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women. N Engl J Med. 2016. https://doi.org/10.1056/NEJMoa1506110 PMID: 26900902

4. Corneli AL, Deese J, Wang M, Taylor D, Ahmed K, Agot K, et al. FEM-PrEP: adherence patterns and factors associated with adherence to a daily oral study product for pre-exposure prophylaxis. J Acquir Immune Defic Syndr. 2014; 66(3):324–31. https://doi.org/10.1097/QAI.0000000000000158 PMID: 25157647

5. Delany-Mor etlwe S, Lombard C, Baron D, Bekker LG, Nkala B, Ahmed K, et al. Tenofovir 1% vaginal gel for prevention of HIV-1 infection in women in South Africa (FACTS-001): a phase 3, randomised, double-blind, placebo-controlled trial. Lancet Infect Dis. 2018; 18(11):1241–50. https://doi.org/10.1016/S1473-3099(18)30428-6 PMID: 30507409

6. Marrazzo JM, Ramjee G, Richardson BA, Gomez K, Mgodi N, Nair G, et al. Tenofovir-based preexposure prophylaxis for HIV infection among African women. N Engl J Med. 2015; 372(6):509–18. https://doi.org/10.1056/NEJMoa1402269 PMID: 25651245

7. Montgomery ET, Mensch B, Musara P, Hartmann M, Woeber K, Etima J, et al. Misreporting of Product Adherence in the MTN-003/VOICE Trial for HIV Prevention in Africa: Participants’ Explanations for Dishonesty. AIDS Behav. 2016.

8. Woodsong C, MacQueen K, Amico KR, Friedland B, Gafos M, Mansoor L, et al. Microbicide clinical trial adherence: insights for introduction. J Int AIDS Soc. 2013; 16:18505. https://doi.org/10.7448/IAS.16.1.18505 PMID: 23561044

9. Corneli A, Wang M, Agot K, Ahmed K, Lombaard J, Van Damm L, et al. Perception of HIV risk and adherence to a daily, investigational pill for HIV prevention in FEM-PrEP. J Acquir Immune Defic Syndr. 2014; 67(5):555–63. https://doi.org/10.1097/QAI.0000000000000362 PMID: 25393942

10. van der Straten A, Stadler J, Montgomery E, Hartmann M, Magazi B, Mathebula F, et al. Women’s experiences with oral and vaginal pre-exposure prophylaxis: the VOICE-C qualitative study in Johannesburg, South Africa. PLoS One. 2014; 9(2):e89118. https://doi.org/10.1371/journal.pone.0089118 PMID: 24586534

11. Lanham M, Wilcher R, Montgomery ET, Pool R, Schuler S, Lenzi R, et al. Engaging male partners in women’s microbicide use: evidence from clinical trials and implications for future research and microbicide introduction. J Int AIDS Soc. 2014; 17(3 Suppl 2):19159. https://doi.org/10.7448/IAS.17.3.19159 PMID: 25224618

12. Montgomery ET, van der Straten A, Stadler J, Hartmann M, Magazi B, Mathebula F, et al. Male Partner Influence on Women’s HIV Prevention Trial Participation and Use of Pre-exposure Prophylaxis: the Importance of “Understanding”. AIDS Behav. 2015; 19(5):784–93. https://doi.org/10.1007/s10461-014-0950-5 PMID: 25461076

13. Myers L. Rethinking PrEP for adolescent girls and young women. IAPAC; June 18, 2019; Miami, FL2019.

14. Celum CL, Delany-Moretwe S, Baeten JM, van der Straten A, Hosek S, Bukusi EA, et al. HIV pre-exposure prophylaxis for adolescent girls and young women in Africa: from efficacy trials to delivery. J Int AIDS Soc. 2019; 22 Suppl 4:e25298.

15. de Dieu Tapsoba J, Zangeneh SZ, Appelmans E, Pasalar S, Mori K, Peng L, et al. Persistence of oral pre-exposure prophylaxis (PrEP) among adolescent girls and young women initiating PrEP for HIV prevention in Kenya. AIDS Care. 2020. https://doi.org/10.1080/09540121.2020.1822505 PMID: 32951437

16. Mugwanya KK, Pintye J, Kinuthia J, Abuna F, Lagat H, Begnel ER, et al. Integrating preexposure prophylaxis delivery in routine family planning clinics: A feasibility programmatic evaluation in Kenya. PLoS Med. 2019; 16(9):e1002885. https://doi.org/10.1371/journal.pmed.1002885 PMID: 31479452

17. Sila J, Lansen AM, Kinuthia J, Owiti G, Abuna F, Kohler RK, et al. High Awareness, Yet Low Uptake, of Pre-Exposure Prophylaxis Among Adolescent Girls and Young Women Within Family Planning Clinics
18. Pintye J, O’Malley G, Kinuthia J, Abuna F, Escudero JN, Mugambi M, et al. Influences on early discontinuation and persistence of daily oral PrEP use among Kenyan adolescent girls and young women: a qualitative evaluation from a PrEP implementation program. J Acquir Immune Defic Syndr. 2020.

19. Cabral A, J MB, Ngure K, Velloza J, Odoyo J, J EH, et al. Intimate Partner Violence and Self-Reported Pre-exposure Prophylaxis Interruptions Among HIV-Negative Partners in HIV Serodiscordant Couples in Kenya and Uganda. J Acquir Immune Defic Syndr. 2018; 77(2):154–9. https://doi.org/10.1097/QAI.0000000000001574 PMID: 29076883

20. Roberts ST, Haberer J, Celum C, Mugo N, Ware NC, Cohen CR, et al. Intimate partner violence and adherence to HIV pre-exposure prophylaxis (PrEP) in African women in HIV serodiscordant relationships: A prospective cohort study. J Acquir Immune Defic Syndr. 2016. https://doi.org/10.1097/QAI.0000000000001083 PMID: 27243900

21. Hartmann M, Lanham M, Palanee-Phillips T, Mathebula F, Tolley EE, Peacock D, et al. Generating CHARISMA: Development of an Intervention to Help Women Build Agency and Safety in Their Relationships While Using PrEP for HIV Prevention. AIDS Educ Prev. 2019; 31(5):433–51. https://doi.org/10.1521/aeap.2019.31.5.433 PMID: 31550193

22. Tolley EE, Zissette S, Martinez A, Palanee-Phillips T, Mathebula F, Tenza S, et al. Development and initial validation of a simple tool to screen for partner support or opposition to HIV prevention product use. PLoS One. 2020; 15(12):e0242881. https://doi.org/10.1371/journal.pone.0242881 PMID: 33351805

23. Feldhaus KM, Koziol-McLain J, Amsbury HL, Norton IM, Lowenstein SR, Abbott JT. Accuracy of 3 brief screening questions for detecting partner violence in the emergency department. JAMA. 1997; 277 (17):1357–61. PMID: 9134940

24. Hegarty K, Fracgp, Bush R, Sheehan M. The composite abuse scale: further development and assessment of reliability and validity of a multidimensional partner abuse measure in clinical settings. Violence Vict. 2005; 20(5):529–47. PMID: 16248489

25. Pipes RB, LeBov-Keeler K. Psychological Abuse Among College Women in Exclusive Heterosexual Dating Relationships. Sex Roles. 1997; 36(9/10):585–603.

26. Pulerwitz J, Gortmaker SL, DeJong W. Measuring Sexual Relationship Power in HIV/STD Research. Sex Roles. 2000; 42(7–8):637–60.

27. Stephenson R, Bartel D, Rubardt M. Constructs of power and equity and their association with contraceptive use among men and women in rural Ethiopia and Kenya. Glob Public Health. 2012; 7 (6):618–34. https://doi.org/10.1080/17441692.2012.672581 PMID: 22568536

28. Stewart RC, Umar E, Tomenson B, Creed F. Validation of the multi-dimensional scale of perceived social support (MSPSS) and the relationship between social support, intimate partner violence and antenatal depression in Malawi. BMC Psychiatry. 2014; 14:180. https://doi.org/10.1186/1471-244X-14-180 PMID: 24938124

29. Montgomery ET, Roberts ST, Reddy K, Tolley EE, Hartmann MW, Ellen, Mathebula F, et al. Impact of the ‘Charisma’ Intervention Pilot on Partner Disclosure, IPV, and Adherence. Conference on Retroviruses and Opportunistic Infections; March 8–11, 2020; Boston, Massachusetts2020. p. 1015.

30. DeVellis RF. Scale development: theory and applications. Fourth edition. ed. Los Angeles: SAGE; 2017. xvii, 262 pages p.

31. Wilson EK, Wagner LD, Palanee-Phillips T, Roberts ST, Tolley EE, Mathebula F, et al. Acceptability and feasibility of the CHARISMA counseling intervention to support women’s use of pre-exposure prophylaxis: results of a pilot study. BMC Womens Health. 2021; 21(1):126. https://doi.org/10.1186/s12905-021-01262-z PMID: 33766006

32. Fuller JL, Tyler JJ, Choi NJ, Young JA, Verhulst SJ, Kovach R, et al. Using indirect questions to detect intimate partner violence: the SAFE-T questionnaire. J Interpers Violence. 2007; 22(2):238–49. https://doi.org/10.1177/0886260506295814 PMID: 17202578

33. McCleary-Sills J, Namy S, Niyo J, Rwemamur D, Salvatory A, Steven E. Stigma, shame and women’s limited agency in help-seeking for intimate partner violence. Glob Public Health. 2016; 11(1–2):224–35. https://doi.org/10.1080/17441692.2015.1047391 PMID: 26156577