Contemporary Clinical Trials Communications 22 (2021) 100782

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: http://www.elsevier.com/locate/conctc

Effect of a storytelling intervention on the retention of serodiscordant couples in ART/PrEP services at antenatal clinic in Namacurra province in Zambézia, Mozambique

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ARTICLE INFO

Keywords:
Mother-to-child transmission of HIV
Male-engagement
PrEP uptake and adherence
Antenatal care
Storytelling

ABSTRACT

Background: Sub-Saharan Africa reported 550,000 new HIV infections among women in 2018. Pregnancy and the postpartum period are associated with an increased risk of HIV acquisition (adjusted risk ratio [RR]: 2.8 during pregnancy and 4.0 in postpartum period vs. non-pregnant or postpartum women, respectively). Acquisition of HIV during pregnancy and breastfeeding increases risk of mother to child transmission. We propose to test the impact of a peer-delivered oral storytelling intervention to increase retention in, and adherence to, pre-exposure prophylaxis (PrEP)/combination antiretroviral treatment (ART) among expectant couples.

Design: We propose a randomized controlled trial (RCT) (35 intervention and 35 control couples) at a health facility where 11% of expectant couples were in serodiscordant relationships in 2018. Couples randomized to the storytelling arm will be visited by a two community volunteers and who successfully adhered to PrEP/ART during a recent pregnancy. This expert couple will orate to participating couples three stories (at 1, 3 and 5 weeks after study enrollment) designed to empower, educate, and establish "ideal" interpersonal communication strategies within couples/families, and support adherence practices among participants. The primary outcome among HIV-uninfected women will be adherence to PrEP at 3 months.

Conclusions: PrEP among at-risk pregnant women must be implemented so that high levels of adherence and retention are achievable for them and their partners. We will test our storytelling intervention to identify an optimal strategy for PrEP education and family engagement in a region with high HIV prevalence. Our results will have an impact by effectively engaging serodiscordant couples in prevention/treatment during pregnancy and beyond.

1. Background

Acquisition of human immunodeficiency virus (HIV) during pregnancy increases mother-to-child-transmission (MTCT) risk [1,2]. The risk of HIV transmission among pregnant and post-partum women is significantly higher when compared to non-pregnant female counterparts; with adjusted risk ratios of 2.82 and 3.97, respectively [3,4]. Pregnant women in Mozambique seroconvert at a rate of 4.28/100 women-years [5], which is similar to published incidence data from Swaziland [6], Uganda [7], and South Africa [2,8]. Among pregnant women in known discordant relationships, HIV incidence is 12.5 per 100 women years [9,10]. In African cohorts, women with incident vs. chronic infection during the pregnancy/postpartum periods had a higher risk of MTCT (odds ratio [OR] 2.3, CI: 1.2–4.4)[10] thus pre-exposure prophylaxis (PrEP) is essential to preventing incident mother and infant HIV infections.

PrEP offers a bridge to partner combination antiretroviral treatment (ART) initiation [11] and viral load suppression (VS) [12]. Among discordant couples, the risk of HIV transmission continues for up to six months post-ART initiation [9,13]. The World Health Organization

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https://doi.org/10.1016/j.conctc.2021.100782
Received 24 May 2020; Received in revised form 1 April 2021; Accepted 28 April 2021
Available online 6 May 2021

(WHO) recommends concurrent usage of ART (for HIV-positive partner) and PrEP (for uninfected partner) for HIV-1 prevention [14]. Integration of PrEP delivery and ART initiation decreased HIV incidence in the negative partner to <0.5% per year [12]. Randomized controlled trials (RCT) have demonstrated that women on PrEP must maintain very high levels of adherence for the drug to be effective [15–17].

Family support can improve uptake of, retention in, and adherence to PrEP among pregnant/lactating women [12,18,19]. Families, including couples, are a proven, effective unit of intervention in the African HIV prevention and care context [20–33]. While couple-centered behavioral interventions have been effective in reducing sexual and drug-risk behaviors, increasing access to HIV testing, and improving uptake of PrEP services [20–37], there are few studies that have assessed the effect of family-centered interventions on adherence to maternal PrEP/paternal ART during pregnancy and lactation [12]. Families cannot provide substantive support to discordant couples unless they have adequate knowledge and skills to do so. Explaining how PrEP works and developing motivational messages that are effective in this population remains a challenge. Eligible patients are offered PrEP at the time of receiving discordant test results, yet discordant couples have little information about PrEP in Zambézia. (unpublished data from Zambézia, Audet et al., 2019). Development of couples-based education and messaging is essential to improving knowledge.

People are seven times more likely to remember a story vs. facts alone [38]. Mozambique has a rich history of oral storytelling, a cultural tradition we will integrate into this intervention. The strength of family support provided to the discordant couple is correlated with adherence to medication and retention in care [39]. Developing and delivering engaging stories has proved essential via numerous RCTs for several reasons: (1) stories act as mnemonic devices for facts [40,41]; (2) stories engage our emotions, which results in increased empathy and adoption of messages [42]; and (3) stories that engage participants lead to story-consistent beliefs [43]. Narratives have been used to persuade patients to accurately assess their risk of a particular condition (e.g. lung cancer, cervical cancer, etc.), in efforts to change behavior (e.g. smoking, condom use, etc.) or uptake specific medical services (e.g. lung cancer screening, human papillomavirus (HPV) vaccination, etc.) [44–48]. Given the history of oral storytelling as an educational tool in Mozambique, there is evidence that this culturally-informed tradition can be used to reduce HIV stigma [49] and increase understanding of complex topics [50,51] like PrEP and ART use.

2. Objectives

The overall goal of this project is to develop and assess the effect of a partner-based PrEP/ART delivery intervention among expectant couples where the pregnant woman is HIV-negative, and her male partner is HIV-positive. Specifically, we will compare the effect of a storytelling intervention (vs. standard of care counseling and clinical services alone) on participants' knowledge, motivation, and behavioral skills associated with PrEP retention and adherence.

2.1. Outcomes of interest

Our primary clinical outcome is PrEP/ART medication non-adherence at three months. Among women, PrEP adherence will be assessed using a urine assay for Tenofovir, with concentrations <100 ng/mL indicative of non-adherence. Additionally, for women lost to follow-up (LTFU), it will be assumed that Tenofovir concentrations are <100 ng/mL. Among men, ART adherence will be assessed using viral load, with viral load ≥200 copies/mL indicative of non-adherence. As for women, men LTFU will be assumed to be not virologically suppressed. Our secondary clinical outcome is not being retained in care at three months, defined as not completing a medical provider visit or prescription refill appointment 90 days (±7 days) after initiation of medication as documented in the ANC logbooks and Open MRS databases.

Other psychosocial outcomes of interest include the impact of the intervention on depression, HIV knowledge, partner support and empathy at 3 months post-enrollment.

3. Study procedures

The proposed study is a two sample, couple-randomized pilot to test the impact of an oral storytelling intervention (versus standard of care PrEP/ART delivery) to increase retention in, and adherence to, PrEP and ART among HIV-discordant expectant couples. The study protocol and informed consent documents have been approved by the Vanderbilt University Medical Center (VUMC) Institutional Review Board (IRB #191719, dated 30 December 2019) and the *Comité Nacional de Bioética para a Saúde* (Institutional Committee for Bioethics in Health in Mozambique, reference #01/CNBS/2020, dated 3 April 2020) in Mozambique. The trial is registered at ClinicalTrials.gov (NCT03149237).

3.1. Site selection

This pilot study will be conducted at Namacurra Sede health facility, a district-level hospital located in Zambézia Province, Mozambique. The site was selected due to the high number of discordant couples eligible for PrEP services.

3.2. Participant selection

Couples, comprised of one pregnant woman and her male partner, will be eligible to participate if: i) the pregnant woman is identified as HIV-negative at antenatal care (ANC)-based HIV testing; ii) the male partner is identified as HIV-positive at any ANC appointment, either through ANC-based HIV testing or having a known history of being HIV-positive (from clinical records or medication pick-up documents, or any other mechanism by which ANC staff identify him as HIV-positive); iii) both persons agree to take PrEP (pregnant woman)/ART (male partner) together and receive standard care in pre- and postnatal period, including care of the HIV-exposed infant at the Child at Risk Clinic (*Consulta de Criança em Risco* [CCR]); iv) the woman's due date is > 4 weeks from study enrollment; v) both persons are 18 years or older; vi) both persons are able to give informed consent; vii) both persons (parents) are willing to consent to an infant record search, and viii) both persons consent to be in the study.

Family members (as defined by relatives living in the participants' household or relatives the participants identify as living in the study community) can be nominated to attend the storytelling sessions by the discordant couple as long as they are 18 years of age or older, are identified as a confidant, and are willing to attend at least one of the storytelling sessions. These family members will be eligible to participate in the qualitative interview about the storytelling session if i) they participated in at least one of the storytelling sessions; ii) are 18 years of age or older; iii) are able to give informed consent; and iv) are willing to participate in the interview.

3.3. Control arm

The participants randomized to the control arm will receive standard of care (SOC) services that include: (1) male engagement (male invitation to ANC services and couples HIV testing); (2) opt-out rapid HIV testing of all pregnant women attending ANC, to ensure patient status [Determine HIV-1/HIV-2®, (Abbott Laboratories, Abbott Park, Illinois, USA) followed by Uni-Gold HIV-1/HIV-2® (Trinity Biotech Plc, Bray, Co. Wicklow, Ireland)]; (3) universal ART services for HIV-positive male partner per national guidelines [52]; (4) counseling for the HIV-

positive partner as per national guidelines; (5) PrEP medications, condoms and psychosocial support/counseling (i.e., PrEP services package as per national guidelines) free of charge; and (6) follow-up HIV testing at time of PrEP medication pick-up (per national guidelines). In addition to SOC services, will offer monthly measurement of PrEP (tenofovir) drug level via urine assay testing [53].

At six-months post-ART initiation, eligible male partners will be referred to one of the differentiated models of care if their viral load (VL) is suppressed (at which point the PrEP regimen for female partner may also be suspended with clinician's approval). If the male partner abandons HIV care and treatment, the woman will continue to be eligible for PrEP. Postpartum women on PrEP will receive follow-up for PrEP services at the adult ART clinic; her infant is followed at the Healthy Child Clinic (*Consulta de Criança Sadia* [CCS]) for clinical follow-up and vaccinations; if the woman seroconverts, she will start ART for life while infants will have access to HIV testing by dried blood spot (DBS) polymerase chain reaction (PCR) testing as early as four weeks after birth at the CCR. If the infant seroconverts, s/he is provided ART for life. In the event of seroconversion for mother, follow-up for mother and infant continues at the CCR until the child is 18 months of age or until two months after the mother ceases breastfeeding (with final diagnosis for infant's HIV status post-exposure). Relevant medications are also offered free of charge in the adult HIV clinic to male partners. If the woman seroconverts at any point during the study, HIV-specific counseling and support, provision of cotrimoxazole prophylaxis, isoniazid preventive therapy (IPT), and universal ART are provided free of charge [54]. Viral load testing is routinely available for all ART-treated children and adults, implemented according to national guidelines.

3.4. Intervention arm

The participants randomized to the intervention arm will receive all of the SOC services and PrEP drug level testing (for females) as described above (i.e., will receive the same SOC clinical services as those couples randomized to the control arm). In addition, the couples randomized to intervention arm will be invited to participate together in three storytelling sessions with eligible family members of their choosing.

The stories were developed based on the experiences of 20 individuals taking PrEP at the study site. This group provided their experiences initiating PrEP, disclosing their discordant relationship status with family and friends, and the challenges to remaining adherent to medication. Positive examples, including those who overcome challenges to remain on PrEP, were extracted and used to create three coherent narratives. The stories will be told by volunteer community members who have successfully completed adhered to PrEP/ART. This “expert” peer couple will deliver the narratives in the first person, each person playing/voicing an assigned character, at the participant couple's home (or in a preferred location chosen by the participants). Each narrative story will last 12–15 min. At the conclusion of the narrative, the trained peer couple will facilitate a discussion with those listening to the story. They will engage the participants and any attending family members in a discussion, asking them about the storyline they just heard. They will ask questions to specifically probe for reactions to events and difficult characters/interactions. They will lead the discussion about ways the main characters in the story (a fictional discordant couple) overcome challenges in adherence to ART/PrEP medication; seeking to learn from the participants if there are ways the stories' messages can be related to their own lives. We will conduct the first two storytelling sessions in the first month of study enrollment to try and influence participants' behavior/thinking prior to their first follow-up visit for medication pick-up (in an effort to assess storytelling's impact on attendance at scheduled appointments, as a proxy for adherence) (Fig. 1).

3.5. Participant assessments

Surveys: Among discordant couples, we will use an interviewer assisted survey consisting of the following measures: (1) depression screening [55]; (2) partner and family support [39,56]; (3) relationship empathy [57]; (4) relationship satisfaction [58]; (5) PrEP stigma [59]; and (6) motivation/perceived ability to adhere to medication [60] at baseline and three months.

Clinical Assessments: For female participants in both study groups, we will measure their PrEP adherence using a point of care (POC) urine test at each medication pick-up for the first three months on the PrEP regimen.

Interviews: We will complete post-intervention qualitative interviews with a smaller sample of participants to gain a better understanding of the perceived positive and negative aspects of the intervention and the overall project. Interviewers will follow a semi-structured interview guide.

4. Statistical analysis

Primary analyses for PrEP/ART adherence biomarker will follow an intent-to-treat protocol. We operationalize the outcome in the negative (e.g., not adherent, such that the odds ratios (OR) for the intervention effect will be < 1.0 if effective. Given the small sample size of $n = 140$ (70 women and 70 men), we will estimate the intervention effect on the dichotomous outcome of non-adherence with a logistic regression model using generalized estimating equations (GEE) and an exchangeable working correlation structure to account for clustering within couples and an interaction term between intervention arm and sex to identify sex-specific intervention effects. The regression model will be further adjusted for education level (none, some primary, completed primary or higher), perceived community HIV stigma (continuous variable), and affective empathy (continuous variable) as these have remained imbalanced at baseline in an earlier couple's intervention study. because the outcome is relatively common ($>30\%$), the magnitude of the OR may exaggerate the magnitude of the relative risk reduction. In addition to reporting crude and adjusted ORs and 95% confidence intervals from the logistic regression model, we will also report regression-based standardized *risk ratios* and 95% confidence intervals [61]. Analysis of our secondary clinical outcome of retention in care at three months will follow the same analysis plan as described above for non-adherence.

For the other outcomes of interest that are psychosocial measures obtained at three months, we will follow a similar analysis plan as described for the clinical outcomes. Because the psychosocial measures are based on scales or indices, outcomes will be continuous and analyzed with linear regression models using GEE and an exchangeable working correlation structure to account for clustering within couples and an interaction term between intervention arm and sex to identify sex-specific intervention effects. The regression model for each psychosocial outcome will be further adjusted for education level and the baseline value of the psychosocial measure of interest (e.g., for analyses of the intervention effect on depression, the model will include the baseline measure of depression).

Prior work on interventions with couples receiving ART indicates that missing data is rare for socio-demographic data. However, for psychosocial measures such as depression or stigma, missingness may reach 10–30%. Given our small sample size, we will utilize multiple imputation methods to retain as much of the sample as possible despite missing data. Because missingness is likely to occur in the psychosocial measures, which are continuous measures and often normally distributed, we will implement joint model imputation (or multivariate normal imputation) on any continuous variables with missing data. Joint model multiple imputation has been shown to be valid for sample sizes as small as 100, even when 30% of data are missing [62].

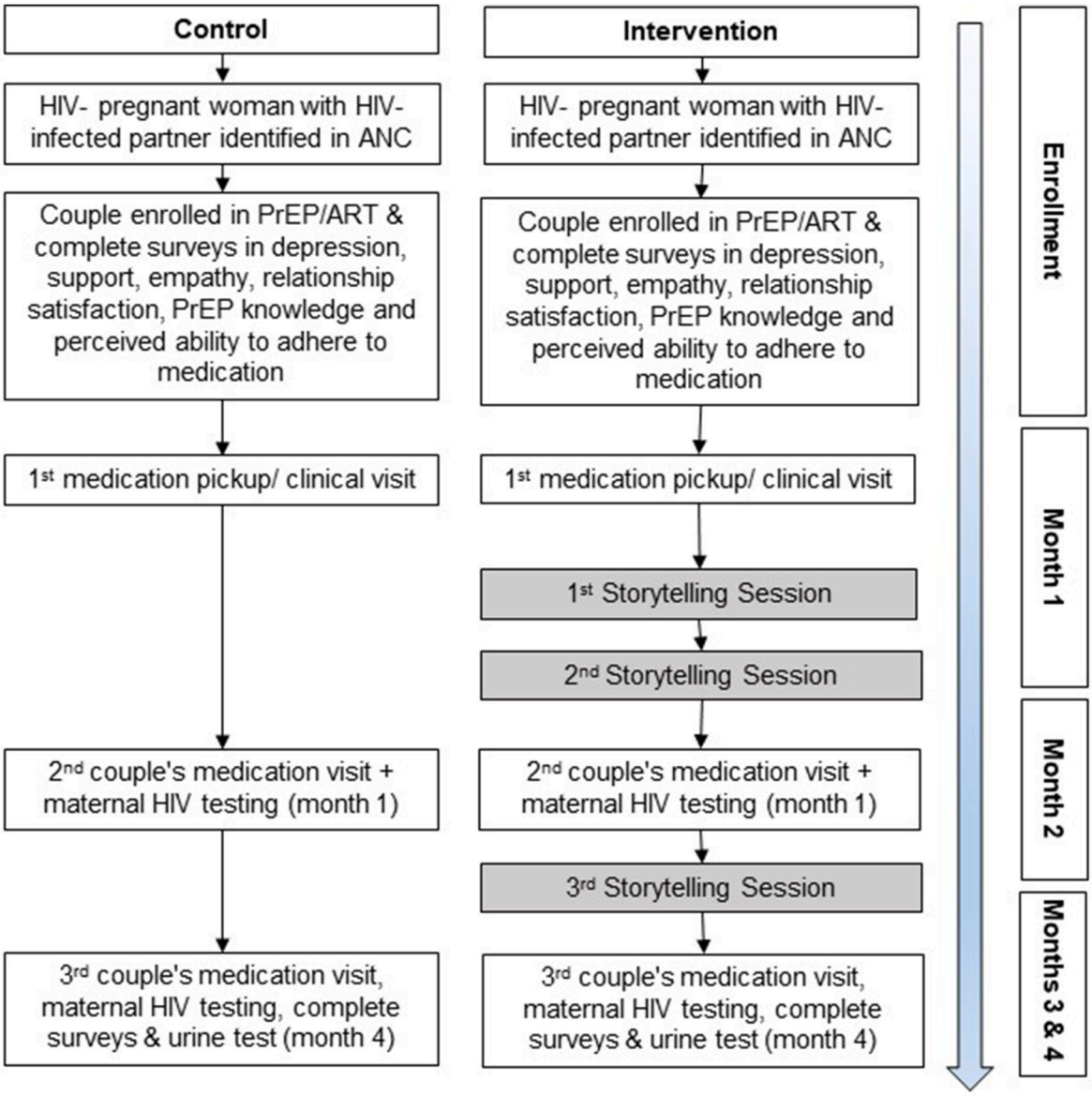

Fig. 1. Timeline of Study Activities.

Qualitative Analyses: Audio files will be transcribed verbatim by a research assistant and two researchers will independently code and analyze the interviews using MAXQDA® software. We will employ a thematic approach to identify and analyze themes in the data [63]. We will focus on two key reactions to the storytelling: (1) the experience of listening to the stories, with a focus on the effectiveness of the narrators' ability to transport the listener, the level of identification and perceived similarity with characters; and (2) the impact of the storytelling intervention on information related to PrEP/ART adherence, with a focus on motivation to adhere to medication due to self-efficacy, family support and feelings of depression/hopelessness, and behavioral skills learned. We will use a combination of deductive codes based on findings from previous adherence research and inductive codes to categorize newly identified factors associated with uptake, adherence, and retention in PrEP/ART services (e.g., self-efficacy, partner support, information etc.). Two researchers will read through the transcripts several times and highlight relevant examples of storytelling impact on information, behavioral skills and motivation. Researchers will generate codes and highlight themes by collating codes across the dataset and review themes to develop a thematic map (e.g., the influence of a character's successful use of a strategy on a listener's self-efficacy to employ the same tactic). The final coding framework will have at least 85% agreement between the two coders. This exercise will allow us to modify our behavioral model if necessary.

4.1. Power and sample size determination

Our pilot will involve 70 couples (70 HIV-negative pregnant women and their HIV-positive male partners; 35 couples in each arm) from a single clinic. Limited data on PrEP in Mozambique suggest 55% of pregnant women were not retained at three months after PrEP initiation (Friends in Global Health [FGH], unpublished routine program data). Given our sample size of 70 women and a 5% type I error, we will have 82% power to detect a RR of 0.40 for not being retained. Should there be evidence the intervention effect is similar for men and women with regards to retention, the two groups can be analyzed together to further improve power to detect RRs closer to 0.50. We do not have estimates of tenofovir levels among PrEP users in Mozambique, but other studies indicate as many as 70% may have no active drug detected [64]. Given our sample of 70 women and a 5% type I error, we will have 85% power to detect a RR of 0.50 for no detectable drug level.

4.2. Limitations

Our sample size of 35 couples in each arm is small, which limits our ability to detect a small change in behavior among couples. However, we believe this pilot will allow us to detect signals of the intervention's success, which we can subsequently use to fund a larger trial.

5. Conclusions/summary

We propose to test the effect of a peer-delivered oral storytelling intervention to increase retention in and adherence to PrEP/ART among serodiscordant expectant couples. We will contrast this model to standard of care services and counseling. This innovative intervention tests a culturally relevant approach (e.g., couples/family engagement via oral storytelling) to ART/PrEP delivery and retention support.

Disclosures

CMA has received compensation from ViiV Healthcare to develop an implementation science curriculum.

Funding

This work is supported by the National Institute of Mental Health (NIMH) grants R01MH113478-01. CMA was also supported by K01MH107255. The authors are solely responsible for the design and conduct of this study, study analyses, and the drafting of this manuscript.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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