A couples-based intervention and postpartum contraceptive uptake in Zambézia Province, Mozambique

By

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It feels entirely surreal writing the acknowledgements to my doctoral dissertation. On the one hand, this is the culmination of years of work that oscillated between periods uncertainty and confusion (what type of bias is it, what is a collider, etc.) with brief moments of unrivaled joy (that one time my code ran the first time) that would not be possible without the support of numerous people. On the other hand, this is the acknowledgements section of a doctoral dissertation and the likelihood that anyone ever reads it, while non-zero, is very low.

All that said, I suppose I should start from the beginning. This would not be possible without my family. I truly do not know where I would be without their unconditional love and support. To my parents, Karen and Michael, who have simultaneously modeled the importance of lifelong learning, confronting the context in which one works, and advocating for what one believes in while providing thoughtful, timely advice and guidance when needed. To my brother, Josh, whose intellect and incisive questions improve how I think about the world and are certainly reflected in how I formulated and addressed the research questions in this dissertation.

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Before I thank the village of people that were integral to this dissertation (my committee, my advisor and her team, etc.), I would like to pause and thank everyone at Shade Tree Clinic – Vanderbilt's medical student run free clinic. Drs. Robert Miller, Eleanor Weaver, Michael Fowler, and Cooper Lloyd – the medical directors – Shannon Jordan – our clinic's social worker – the excellent group of students I have worked with for the last six years in various roles, and, most importantly, the patients that I've had the privilege to get to know. It also created a sense of community and common cause when the world was shut down that, frankly, kept me mentally well.

As I mentioned before, this would not be possible without a village of people. First, I need to thank all the HoPS+ trial participants for participating and literally making this project possible. This would not have been possible without Dr. Carolyn Audet's excellent team, who organized participant recruitment, data collection, and general HoPS+ operations. Among an outstanding group, Erin Graves (based in Nashville) and Ariano Matino (based in Mozambique) stand out. They were endlessly patient with my many, often selfish, questions.

In Nashville, I had the support of kind, generous, and brilliant committee members. Dr. Katherine Hartmann, who actually called me after my interview with the MD/PhD program to chat about the epidemiology program because she was out of town when I was interviewing, always brings thoughtful probing questions that have improved my

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LIST OF ABBREVIATIONS

ANC – antenatal care
ART – antiretroviral therapy
CBPS – covariate balancing propensity score
CD4 – helper T cell
CI – confidence interval
COVID-19 – coronavirus disease 2019
DOF – degree of freedom
GEE – generalized estimating equations
HIV – human immunodeficiency virus
HoPS+ - Homens para Saúde Mais [Men for Health Plus]
ICC – intracluster correlation
IQR – interquartile range
LAM – lactational amenorrhea
MD – Mancl DeRouen
MMM – marginalized multilevel model
OLS – ordinary least squares
OR – odds ratio
ORM – ordinal regression model
PEPFAR – President's Emergency Plan for AIDS Relief
PLW – pregnant and lactating women
Q1 – first quartile
Q3 – third quartile
UNAIDS – Joint United Nations Programme on HIV/AIDS
USAID – United States Agency for International Development
WHO – World Health Organization

1. Background

Efforts to increase postpartum contraceptive uptake are essential to prevent the negative maternal and fetal outcomes associated with short inter-pregnancy intervals, which are often the result of unintended – mistimed or unwanted – pregnancies.[1–5] Postpartum contraceptive uptake reduces unintended pregnancy and improves psychosocial, medical, and economic outcomes among women who are able to plan and time their pregnancies.[6] For people living with HIV, healthy timing and spacing of pregnancy is also essential to allow time for adequate viral suppression to reduce maternal-to-child HIV transmission.[3,7] Recognizing this, the World Health Organization (WHO) highlighted preventing unintended pregnancies as a key component of preventing maternal-to-child HIV transmission in 2002.[8] In 2006, the African Union declared universal access to reproductive health an essential component of combatting the HIV epidemic in Africa and meeting the Millennium Development Goals.[9] To support effective implementation of reproductive health services, the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommended integrating contraceptive counseling into HIV care to increase postpartum contraceptive uptake.[10] These commitments coincided with shifting HIV treatment guidelines during pregnancy, culminating with Option B+ in 2012, which recommended lifelong antiretroviral therapy for all pregnant people living with HIV regardless of CD4 count and promoted the integration of antiretroviral therapy and prevention of maternal-to-child transmission services.[11]

Given the important role contraception plays in improving maternal and fetal health and reducing maternal-to-child HIV transmission among people with HIV who are not yet virally suppressed, several groups have published guidelines recommending healthy

interpregnancy intervals. In 2005, the WHO recommended that a woman wait at least 24 months after a live birth before attempting another pregnancy (although a contingent felt that the data only supported waiting 18 months) to minimize the risk of adverse maternal and child outcomes.[12] They specified that repeat pregnancies less than six months from live birth are associated with higher maternal mortality and repeat pregnancies less than 18 months from live birth are associated with worse infant, neonatal, and perinatal outcomes (with some evidence suggesting deleterious effects up to 27 months).[12] Of note, they also commented that long interpregnancy intervals can be deleterious to infants and mothers (greater than 5 years).[12] A 2019 American College of Obstetricians and Gynecologists recommendation described the interpregnancy period as a time to optimize a woman's health and, if another pregnancy is desired, to improve maternal health prior to subsequent pregnancy.[13] They recommended a minimum interpregnancy interval of 18 months and against repeat pregnancy prior to six months after live birth.[13] Both organizations reported that deleterious outcomes from short interpregnancy intervals include, but are not limited to, preeclampsia, unsafe induced abortion, stillbirths, pre-term birth, premature rupturing of membranes, low birthweight, small for gestational age, and uterine rupture.[12,13] Recent data suggest that deleterious outcomes with short interpregnancy intervals may be limited to intervals less than six months in duration in high resources settings,[14] which may support a theory that folate depletion during pregnancy persists and negatively impacts subsequent pregnancies with short interpregnancy intervals.[15,16] Short interpregnancy intervals may also be associated with other predictors of poor pregnancy outcomes – smoking, substance use, poor nutrition, later prenatal care initiation, etc. –

which may confound the relationship between short interpregnancy intervals and poor birth outcomes.[14,17] Other advantages to intentional birth spacing include a family's ability to clothe, feed, shelter, and educate offspring in low resource settings and nutritional replacement in a mother after delivery.[12,15,18]

Pregnant people with HIV are more likely to experience preterm birth and low birthweight offspring than pregnant people without HIV,[19] which may be exacerbated by inadequate birth spacing.[12,13] Furthermore, earlier antiretroviral treatment initiation during pregnancy and HIV viral suppression substantially decreases the risk of maternal-to-child HIV transmission.[20,21] Appropriate interpregnancy intervals therefore, in addition to healthier pregnancies in general for people with HIV, allows for improved HIV management, leading to viral suppression and reduced maternal-to-child HIV transmission.[13] This especially relevant given the high rate of unintended pregnancy in people living with HIV in SSA (56%) and the increased rate of maternal-to-child HIV transmission during unintended compared to intended pregnancies among people with HIV.[7] Postpartum contraceptive uptake therefore, in addition to being an important component of preventing maternal-to-child HIV transmission,[8] is essential to facilitating healthy interpregnancy intervals and the associated health benefits.[12,13]

Defining effective postpartum contraceptive methods that allow for appropriate birth spacing, however, has not been entirely uniform across studies assessing programs aimed at increasing postpartum contraceptive uptake across sub-Saharan Africa (Sack et al. 2022, Contraception, Under Review). For example, some studies have considered lactational amenorrhea (LAM) for the first six months of the postpartum period as "modern",[22–24] whereas others have not specified whether LAM was "modern" or

"traditional".[25] Daniele et al. (2018) and Harrington et al. (2019) defined "modern" methods as, "effective modern methods" based on methods having a typical use failure rate of less than ten percent,[26,27] with Harrington et al. (2019) further specifying that the "modern" methods had to available at their study sites (sterilization, implant, copper IUD, injectable, and oral contraception). Additionally, Villar-Loubet et al. (2012) and Atukunda et al. (2021) included barrier methods as "modern" (only condoms in Villar-Loubet et al.'s case) if study participants reported using them with every sexual encounter.[28,29] For the sake of this dissertation, I defined "modern postpartum contraceptives" as methods included in Hubacher and Trussell's (2015) definition – sterilization, intrauterine devices, implants, oral contraceptives, injectables, emergency contraceptive pills, patches, diaphragms and cervical caps, spermicidal agents, vaginal rings, and sponges – because other potentially effective methods, such as LAM, are only highly efficacious for six months postpartum,[30] which is shorter than the recommended interpregnancy intervals for healthy timing and spacing of pregnancy.[12,13,31]

Despite the focus on integrating contraception into HIV care in sub-Saharan Africa,[10] up to 60% of women living with HIV report unmet contraceptive needs[32] – defined as wanting to use, but not having access to, contraception for any reason – and only 7 to 48% of women of reproductive age in sub-Saharan Africa report any postpartum contraceptive use.[33] In Mozambique, only 32% of women have their contraceptives needs met in the postpartum period.[33] For women living with HIV, this gap in service delivery is leads to a higher risk of mother-to-child HIV transmission.[3,7]

1.1 Strategies to Increase Contraceptive Uptake

Contraceptive uptake is tied to social, cultural, economic, and health system norms.[3] Efforts to promote contraceptive uptake cannot overlook how contraceptive methods have been used to promote white supremacy, colonialism, and sexism, particularly in Southern Africa. In South Africa, for example, the racist apartheid government prioritized providing contraceptives to Black South Africans to limit their fertility.[34–36] They built robust infrastructure to deliver certain types of contraceptives, long-acting injectables, to areas with large numbers of Black South Africans at the expense of other forms of contraceptives or other health services.[34–36] After Zimbabwe gained independence from the British in the 1980s, the new government banned injectable contraceptives, which they viewed as a form of medical colonialism aimed at limiting Zimbabwean population growth.[37] While some viewed long-lasting contraception with disdain, some Zimbabwean women took advantage of injectable contraceptives' surreptitious nature (no pills or devices for partners to find) to take control of their fertility in spite of the norm – male partner dominance in their medical decision-making.[37] In Mozambique, Portuguese colonial rule (1890s-1974) encoded Catholic prohibitions on birth control and abortion into civil law.[38] After independence, Mozambique's ruling party initially allowed contraceptives in 1976 – although they only became available much later – to allow for birth spacing rather than overall fertility control (i.e., motherhood was still assumed as the proper role for women in society).[38] This complicated history shapes how individuals and families, and the societies they operate within, approach fertility decisions and is an important consideration for public health professionals and clinicians working to improve consensual contraceptive uptake.

In sub-Saharan Africa, strategies that engage male partners to improve intra-couple communication have decreased unmet contraceptive needs.[39–41] Exner et al. (2009) showed that engaging males increased condom use among Nigerian men during their last sexual encounter from approximately 48% to 79%,[39] Shattuck et al. (2011) identified that partner communication is an essential component of increased contraceptive use in Malawi,[41] and Mosha et al. (2013) reported that low health literacy and disengagement among male partners may inhibit women's contraceptive uptake in Tanzania.[40] A more recent trial, Daniele et al. (2018), found slightly higher postpartum contraceptive uptake (6.4% increased use at eight months postpartum) after three educational sessions in perinatal care: a male partner and a couples session during pregnancy, and a postnatal couples counseling session.[27] These successes suggest that incorporating interventions that integrate male partners into existing maternal health systems is a promising avenue for future work.

Efforts to further explain poor modern contraceptive uptake in Mozambique highlight the role of religion, fertility intention, gender dynamics, and other sociocultural determinants of contraceptive utilization.[42–44] Agadjanian and Hayford (2018) argue that since the implementation of universal postpartum anti-retroviral therapy in 2013,[10] women stopped seeing their HIV diagnosis as a death sentence and have begun using contraception to time their pregnancies and improve their and their children's health outcomes.[43] Mboane and Bhatta (2015) found that 28.4% of Mozambican women report that their male partner makes their reproductive health decisions,[45] highlighting the importance of a culturally tailored strategy to increase contraceptive uptake in Mozambique.

1.2 Male Partner Influence on Contraceptive Uptake

Male partners play a pivotal role in women's reproductive choices and engagement in HIV treatment and care.[7,26–28,45–58] A review of strategies to improve postpartum contraceptive uptake in lower and middle income countries identified facility- and community-based interventions that incorporated partners into pre- and/or postnatal care.[25,56,59–62] Interventions engaging both partners, whether facility- or community-based, increased postpartum contraceptive use more than interventions only targeted to female partners.[25,56,59–62] Blackstone et al. (2017) highlighted the stark power imbalance inherent to reproductive health decisions in much of sub-Saharan Africa.[55] Though they found that male partners can have a negative impact on contraceptive uptake and simultaneously that relationship satisfaction can increase contraceptive use.[55] As part of my work for this dissertation, I led a systematic review of couples-based interventions and modern postpartum contraceptive uptake (Sack et al. 2022, Contraception, Under Review), which included risk of bias assessments for randomized and observational studies.[63,64] **Table 1** shows a summary of the strategies adjudicated as at low risk of bias, and their related findings on postpartum contraceptive uptake in several countries.[22,25,27,60,65,66]

Table 1. Strategies to increase contraceptive uptake (studies in chronological order)

Study	Country	Design	Sample Size (clusters)	Intervention	Outcome	Risk Difference (95% CI)
Saeed et al. 2008[60]	Pakistan	RCT	600	Educational leaflets and counseling in the postnatal ward	Contraceptive use at 8-12 weeks postpartum	0.51 (0.44, 0.57)
Ahmed et al. 2015[25]	Bangladesh	Quasi-experimental	4083 (4)	Behavior change communication related to postpartum contraceptive added to existing interpersonal counseling and group meetings in ante- and postpartum care	Contraceptive adoption and continuance at 24 months postpartum	0.10 (no CI)
Daniele et al. 2018[27]	Burkina Faso	RCT	1115	3 educational sessions: a male partner and a couple's session during pregnancy, and a postnatal couple counseling session.	Effective modern contraceptive use 8 months postpartum	0.06 (0.01, 0.12)
Harrington et al. 2019[65]	Kenya	RCT	254	Weekly text messages with information about contraceptives tailored to gestational age or postpartum week, male partner could opt in	Effective modern contraceptive use 6 months postpartum	0.13 (0.01, 0.24)
Tran et al. 2019[22]	Burkina Faso	cRCT	523 (8)	3 facility interventions for providers, 3 individual interventions to increase contraceptive knowledge, male partner invitation letter included	Effective modern contraceptive use 12 months postpartum	0.26 (0.18, 0.34)
Atukunda et al. 2021[66]	Uganda	RCT	317	Immediate postpartum contraceptive counseling session with both partners	Modern contraceptive use 12 months postpartum	0.11 (0.01, 0.2)

RCT: Randomized Controlled Trial; cRCT: Cluster Randomized Controlled Trial; CI: Confidence Interval

Our review found that across the 18 interventions assessed, all reported a positive or null association between couples-based interventions and postpartum family planning uptake (Sack et al. 2022, Contraception, Under Review). Unfortunately, the intervention protocols and outcome definitions were too heterogenous to support meta-analysis or policy suggestions. Furthermore, different levels of adherence among male partner participants further limited the conclusions. A related review of interventions that work within existing gender norms or promote gender equality in reproductive health (contraception, breastfeeding, age at first marriage, etc.) noted either improved or null effects on contraceptive uptake, but highlighted the difficulty in defining causal pathways between gender dynamics and health outcomes.[48]

1.3 HIV and Postpartum Contraceptive Uptake

The integration of universal antiretroviral therapy and contraceptive services for postpartum women provides an ideal opportunity to explore drivers of uptake of, and continued support for, contraceptives among a vulnerable population with unmet contraceptive needs.[67] Doing so requires a multi-faceted analysis that leverages the strengths of the interpretive and positivist research paradigms.[68] This thesis, situated within a cluster randomized controlled trial, substantively adds to the knowledge base of how male partner engagement in prenatal care impacts postpartum modern contraceptive uptake. Integration of qualitative and quantitative methods will allow for a more thorough investigation of the causal pathways that exist between couples-based interventions and favorable reproductive health outcomes. The interpretive paradigm (Aim 1), embedded in qualitative research, elucidates how individuals understand their modern postpartum contraceptive use decision within the social, cultural, political,

economic, and historical contexts in which they live.[68] The positivist paradigm (Aims 2 & 3), inherent to quantitative research, measures and provides effect estimates for how male partner integration into prenatal care impacts modern postpartum contraceptive use through appropriately powered, well-designed studies.[68] Identification of drivers of modern postpartum contraceptive uptake in women living with HIV through this mixed-methods project will allow policy makers, health care systems, and community members to develop and implement targeted strategies to improve postpartum contraceptive uptake in women living with HIV, which will prevent deleterious health outcomes for mothers and their children.[1,2]

1.4 Strengths of the Proposed Project

In this proposal, I build on a well-designed, cluster randomized clinical trial – Homens para Saúde Mais (HoPS+) [Men for Health Plus][69] – to answer a question that will improve the lives of women in a resource-limited setting. This project draws on the strengths of diverse mentorship across anthropology and epidemiology (Dr. Audet), biostatistics (Dr. Shepherd), and builds on Dr. Audet's ten-year collaboration with *Friends in Global Health* in Zambézia Province, Mozambique. My dissertation committee brings further expertise in epidemiology, HIV, and obstetrics and gynecology (Drs. Katherine Hartmann, Peter Rebeiro, and Sarah Osmundson). Specifically, this dissertation will:

- Add to the sparse literature on postpartum modern contraceptive behavior, specifically examining postpartum contraceptive uptake in an understudied region, at the intersection of East and Southern Africa, and among women living with HIV – an understudied population (Table 1).

- Leverage the interpretive research paradigm to gain insight into the key drivers of postpartum contraceptive choice among women living with HIV from the perspective of women and their partners (Aim 1).
- Assess how a multi-faceted, randomized couples-based intervention impacts postpartum behavior – modern contraceptive uptake and repeat pregnancy – in couples living with HIV (Aim 2).
- Determine how intervention fidelity impacts postpartum modern contraceptive uptake in women living with HIV (Aim 3) to generate hypotheses that will inform future trials that aim to increase postpartum contraceptive uptake.

These findings will provide researchers and policy makers with data to create interventions to increase postpartum contraceptive uptake in women living with HIV at the intersection of East and Southern Africa.

2. Study Design

This dissertation is situated within the Homens para Saúde Mais (HoPS+) [Men for Health Plus] trial. The HoPS+ trial is an extension of Dr. Audet's ongoing work in Mozambique focused on increasing male partner engagement in antenatal care and HIV testing.[46,47]

HoPS+ is a clustered randomized controlled trial that explores how **incorporating male partners into pre- and post-natal care among seroconcordant couples with HIV** influences retention in and adherence to treatment, and mother-to-child transmission. Participants completed a baseline demographic survey and clinical outcomes including, but not limited to, HIV viral load, antiretroviral therapy adherence, and contraceptive initiation and continuation were tracked for the duration of their enrollment via patient questionnaires and the medical record (18 months) (**Appendix 1**).

Participants also completed assessments of depression, empathy, social support, HIV stigma, provider trust, and HIV knowledge at baseline and six months with repeated depression and empathy assessments at 18 months (**Appendix 2**). Our group has validated the HIV knowledge scale[70] and Interpersonal Reactivity Index (empathy),[71,72] and assessed depression in 3,543 women (Patient Health Questionaire-9, which has also been independently validated in Mozambique)[73,74] in Zambézia Province, Mozambique. The HoPS+ team has also validated the other psychometric instruments – Berlin Social Support Scale,[75] Van Rie HIV Stigma Scale,[76] and Hall et al. Medical Profession Trust Scale (Frisby et al., 2021, AIDS and Behavior, Under Review).[77]

Zambézia Province is a rural province home to approximately 5.1 million people located in north-central Mozambique.[78] Zambézia has some of the lowest health and

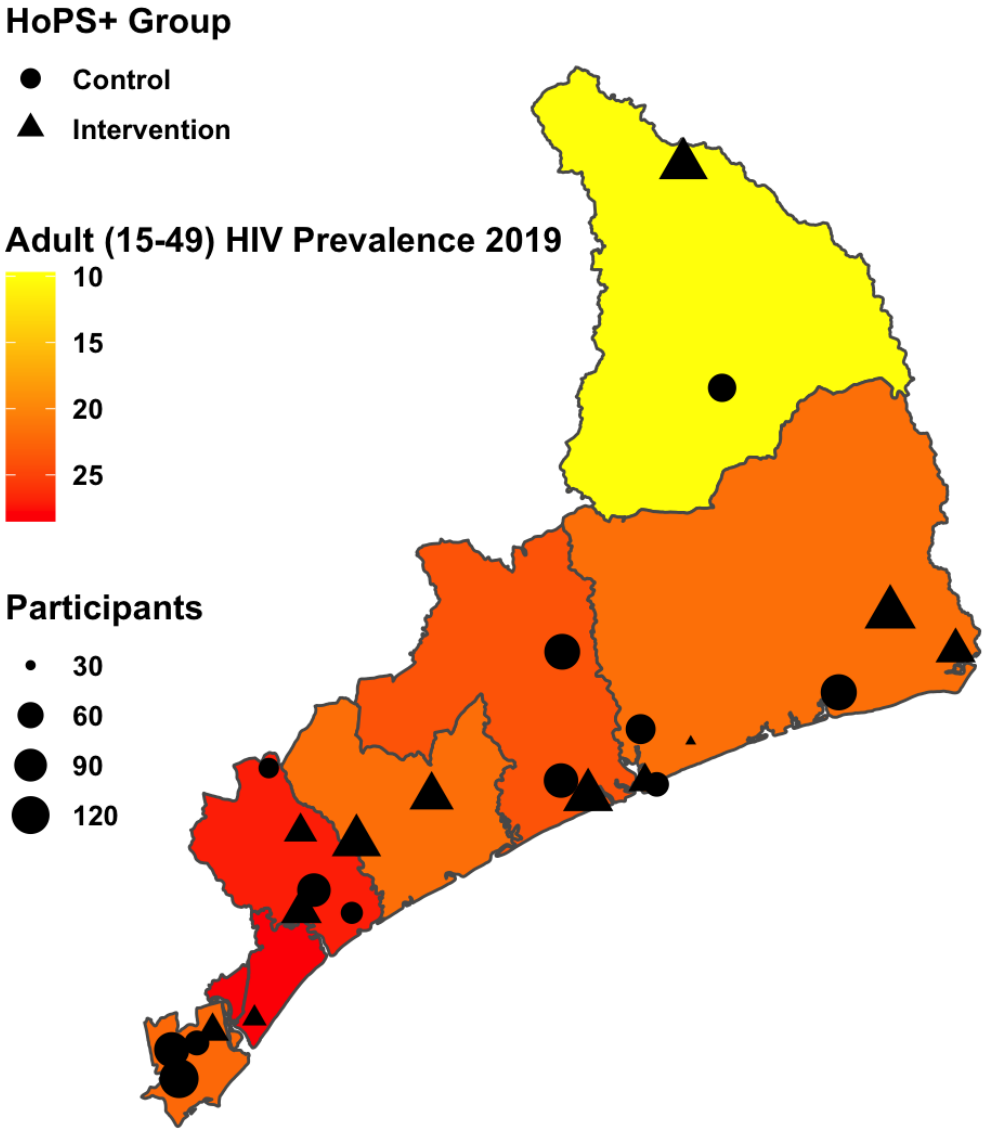
development indicators in Mozambique.[79] A 2015 United States Agency for International Development (USAID) report found, for example, that despite multiple programs in Zambézia from 2009 to 2015, there were insufficient water access points and sanitation services for a large proportion of residents, which led to contaminated water sources across the province.[79] While HIV prevalence in Mozambique is 13%, approximately 15% of adults in Zambézia were living with HIV in 2015.[80] Among people living with HIV in Zambézia in 2015, 30% were on treatment and 50% of people on treatment were virally suppressed.[80] The Mozambican Ministry of Health provides the following modern contraceptive methods free of charge at all maternity wards and postpartum care visits: combined contraceptive pills, progesterone-only pills, injectables (both intramuscular and subcutaneous), copper intrauterine devices, implants, tubal ligation (female sterilization), vasectomy (male sterilization), condoms (male and female), and an emergency contraceptive pill (personal communication, 2021). Unfortunately, several stock outs during the study period may have impacted contraceptive availability. For example, during the first half of 2021, injectable contraceptives were not available. During stock outs, women were offered alternative contraceptives (personal communication, 2021).

2.1 Eligibility Criteria

Eligible couples included pregnant women with HIV and their male partner with HIV, both older than 18 years old, presenting for antenatal care services together at one of 24 clinic sites in Zambézia Province. Both partners must not have been on antiretroviral therapy for 60 days prior to study enrollment – either due to being treatment naïve or lost to follow-up – both partners agreed to take antiretroviral therapy together and

receive ante- and post-natal care for themselves and their child, the woman's due date must have been greater than two weeks from study enrollment, and both participants must have been willing and able to provide informed consent for themselves and their children. Couples were able not able to participate if either member was less than 18 years-old, HIV negative, or if either member of the couple did not or was not able to consent to participation for themselves or their infant. Couples were enrolled at each study site on a first come, first serve basis until there were approximately 45 couples per site. Clinics were randomized in pairs into standard of care (12 clinics) and intervention (12 clinics) after matching on anti-retroviral therapy uptake rate, retention in care among patients on treatment, patient volume, HIV prevalence in antenatal care, and facility level (secondary or primary)[81] using reweighted Mahalanobis distances.[82] Intervention and standard of care sites were >100 km from each other to prevent cross-talk between couples enrolled in each study arm. **Figure 1** shows the location of each clinic within Zambézia Province, Mozambique. The shapes and sizes of the circles and triangles show the type of clinic and the number of enrolled participants. Each district is colored on a yellow-red gradient that indicates the HIV prevalence among 15-49 year-olds living with HIV in 2019, with red indicating a higher prevalence.[83]

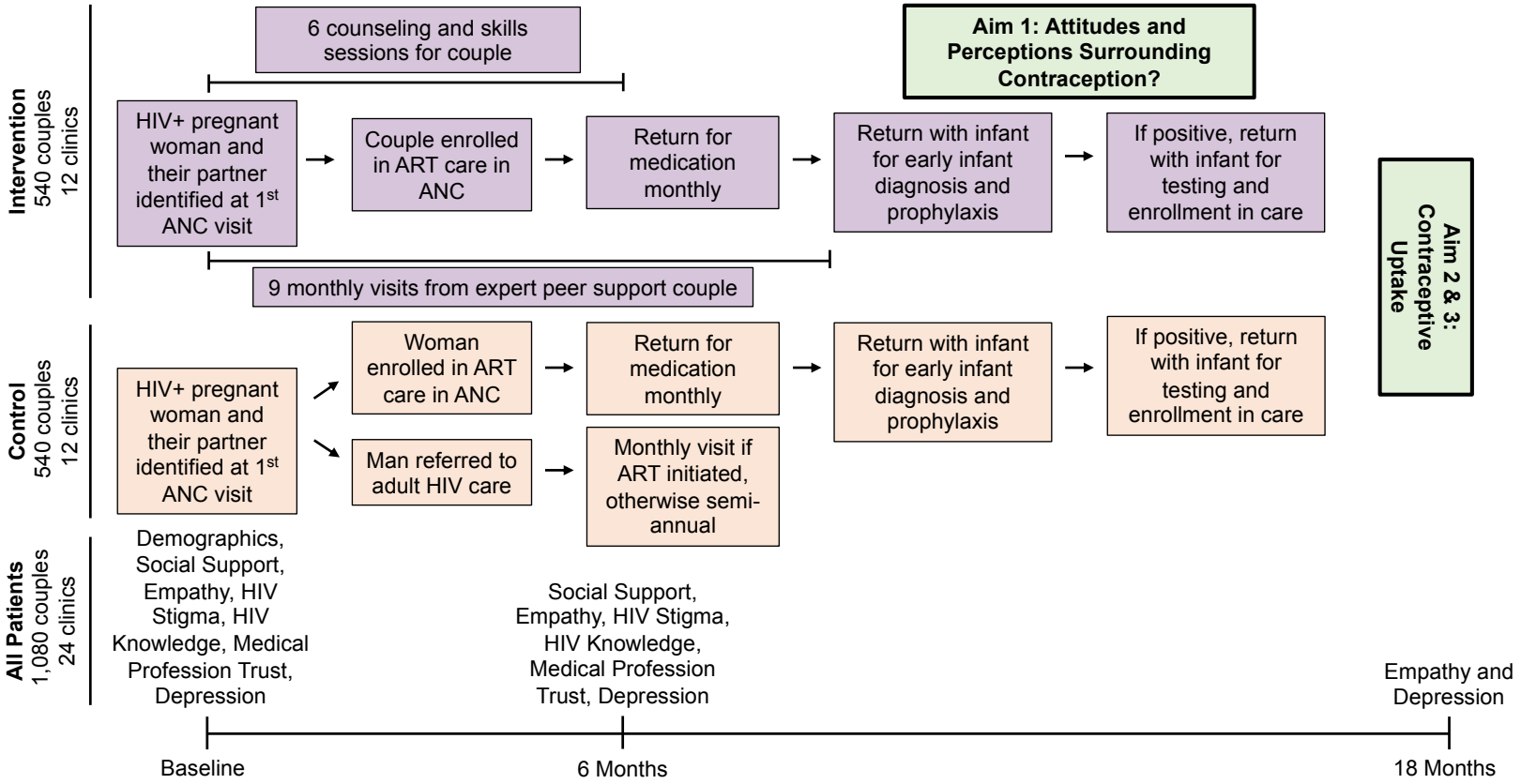
Figure 1. HoPS+ clinic locations and district-level HIV prevalence, Zambézia Province, Mozambique



Participants in the control group received the standard of care prenatal HIV treatment, which included prenatal care and monthly visits for medication refills for the female and male partner separately. Participants in the intervention group, in addition to routine prenatal care, attended joint monthly visits for medication refills for their HIV care. They also participated in six couples counseling and skills sessions (**Appendix 3**) that

included discussions about communication, shared decision making, and conflict resolution, including how these topics relate to contraception, as well as education about HIV aimed to improve HIV knowledge and decrease HIV stigma. Finally, participants in the intervention group were paired with an expert peer support couple, who had completed the six counseling and skills sessions, to provide them with guidance – through nine monthly visits – during the prenatal period.[69] These interventions are hypothesized to work in concert to improve maternal retention in care and adherence to treatment and reduce maternal-to-child HIV transmission.[69] **The HoPS+ trial provided an opportunity to gain insight into how engaging male partners in prenatal care influences postpartum contraceptive uptake in women living with HIV in Zambézia Province, Mozambique** – **Figure 2.**

Figure 2. Homens para Saúde Mais (HoPS+) [Men for Health Plus] Trial



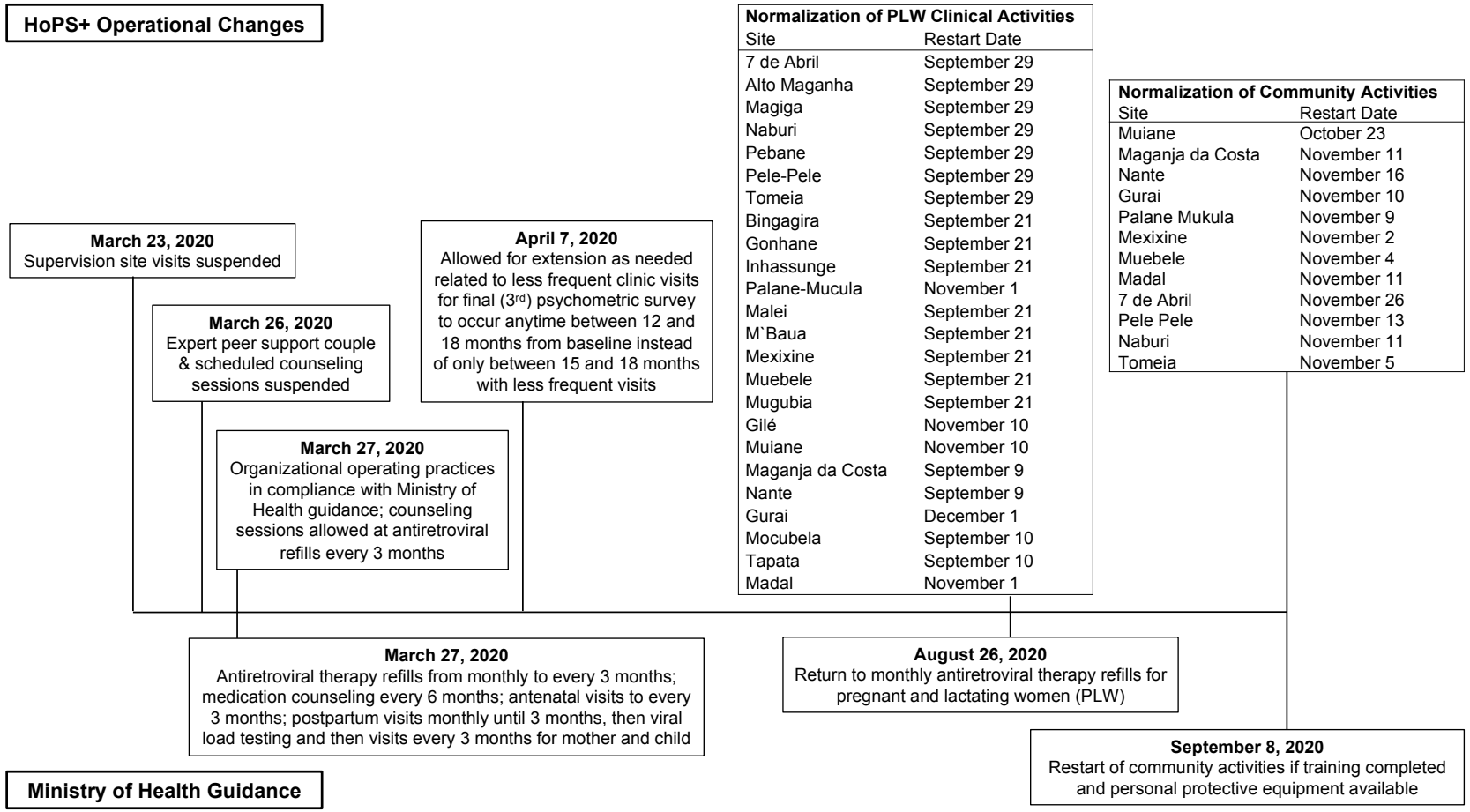
ART: Antiretroviral Therapy; ANC: Antenatal Care

2.2 The World Turns Upside Down

Coronavirus Disease (COVID-19) had implications for this research. Although the HoPS+ trial continued recruiting; the pace of recruitment slowed dramatically after March 2020, which delayed full enrollment. As such, this dissertation only included data from participants with outcome data as of November 30, 2021. Any publications generated from this dissertation will be delayed until the full dataset is available.

COVID-19-induced protocol changes are presented in **Figure 3**. On March 26, 2020, peer support sessions were suspended per Ministry of Health guidance. Furthermore, most patients moved from monthly medication visits to visits every three months and, for couples in the intervention group, joint counseling sessions were moved to align with these visits. Participant interviews (relevant for Aim 1) were temporarily paused in May 2020. Clinical activities for pregnant and lactating women started to resume in September 2020 and community activities started to resume in October 2020. In my analyses, I attempted to anticipate challenges specific to each aim with appropriate sensitivity analyses, including in the power calculations below (**Chapter 2, Section 4, Page 21**).

Figure 3. COVID-19-induced HoPS+ protocol changes



Normalization of PLW Clinical Activities

Site	Restart Date
7 de Abril	September 29
Alto Maganha	September 29
Magiga	September 29
Naburi	September 29
Pebane	September 29
Pele-Pele	September 29
Tomeia	September 29
Bingagira	September 21
Gonhane	September 21
Inhassunge	September 21
Palane-Mucula	November 1
Malei	September 21
M`Baua	September 21
Mexixine	September 21
Muebele	September 21
Mugubia	September 21
Gilé	November 10
Muiane	November 10
Maganja da Costa	September 9
Nante	September 9
Gurai	December 1
Mocubela	September 10
Tapata	September 10
Madal	November 1

Normalization of Community Activities

Site	Restart Date
Muiane	October 23
Maganja da Costa	November 11
Nante	November 16
Gurai	November 10
Palane Mukula	November 9
Mexixine	November 2
Muebele	November 4
Madal	November 11
7 de Abril	November 26
Pele Pele	November 13
Naburi	November 11
Tomeia	November 5

PLW: Pregnant and lactating women

2.3 Specific Aims

Specific Aim 1: Develop a thematic map within the information, motivation, and behavior model,[84,85] through inductive and deductive coding, that frames perceptions of, attitudes towards, and experiences with modern contraceptive use among HoPS+ seroconcordant couples with HIV.

> **Hypothesis 1:** Perceptions of, attitudes towards, and experiences with modern contraceptive uptake will be influenced by each woman and her male partner's contraceptive knowledge and fertility intentions.

Specific Aim 2: Quantify the impact of HoPS+ on modern postpartum contraceptive initiation and continuance and repeat pregnancy during the 12 months after live birth among women living with HIV.

> **Hypothesis 2:** Women in the intervention group will have a higher odds of modern postpartum contraception initiation and continuance and a lower hazard of repeat pregnancy after live birth than those in the control group.

Specific Aim 3: Assess the dose-response relationship between HoPS+ components – counseling, peer support, and prenatal visits – in the intervention group and prenatal visit attendance in the control group and modern postpartum contraceptive initiation and continuance during the 12 months after live birth.

> **Hypothesis 3:** For each additional counseling and skills session, expert peer support couple session, and prenatal visit attended, women in the intervention group will have increased odds of modern postpartum contraceptive initiation and continuance during the 12 months after live birth.

Hypothesis 4: For each additional pre-natal visit attended, women in the control group will have increased odds of modern postpartum contraceptive initiation and continuance during the 12 months after live birth.

These aims will be directly relevant to HoPS+ participants and generalizable to women living with HIV in other rural areas in sub-Saharan Africa. My findings will also inform further research questions relevant to a broader group of women living with HIV. They will inform policy surrounding optimizing interpregnancy care for women living with HIV to minimize HIV transmission and optimize maternal and infant health outcomes.

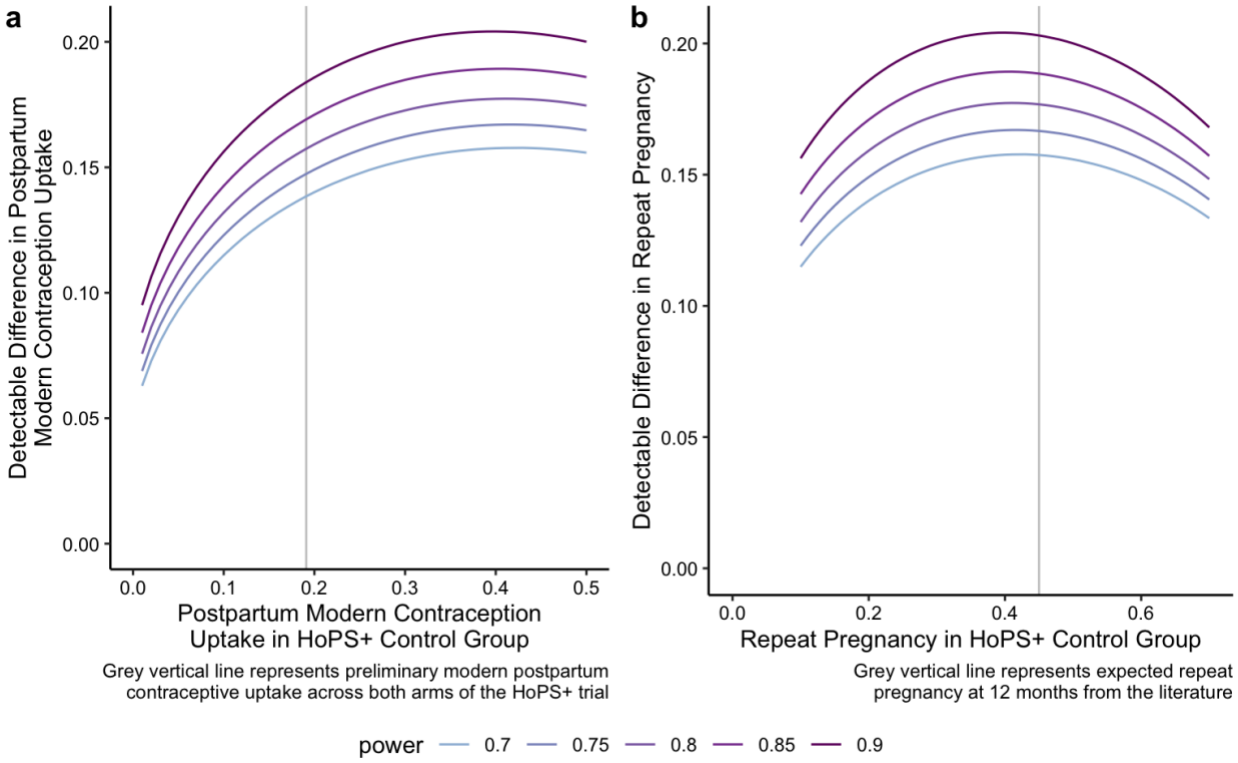
2.4 Power Calculations for Quantitative Aims

Prior to embarking on the analyses outlined in the following chapters, I conducted the following power calculations.

2.4.1 Power Calculation Aim 2: With an anticipated 1,080 women enrolled in the HoPS+ trial across 24 sites (approximately 45 women per site), I anticipated that I would have approximately 80% power to detect an 15% (i.e. 11.6% vs 26.6%) absolute difference in the percentage using modern contraception 12 months from live birth.[33,86] This calculation used an α of 0.05, is based on previous preliminary data that 19.1% of women were using postpartum modern contraception, and accounted for the clustered nature of the data assuming an intracluster correlation of 0.07 (from the original HoPS+ power calculations).[69,86] Simulating modern postpartum contraceptive uptake in the control group from 1% to 50%, I found the detectable proportion differences at an α of 0.05 and powers of 70 to 90% represented in **Figure 4a**. The lower the modern postpartum contraceptive uptake in the control group, the smaller the detectable difference. I anticipated approximately 80% power to detect an absolute difference of

16.5% (i.e., 28.5% vs. 45%) in repeat pregnancy 12 months after a live birth with an α of 0.05, assuming a repeat pregnancy rate of 45% in the standard of care arm and an intracluster correlation of 0.07 (secondary outcome).[33,86] I also simulated repeat pregnancy 12 months after live birth from 10% to 70% in the control group with powers of 70 to 90% (**Figure 4b**). Both of these power calculations were likely conservative because covariate adjustment with a randomized exposure increases statistical power and effective sample size.[87–89]

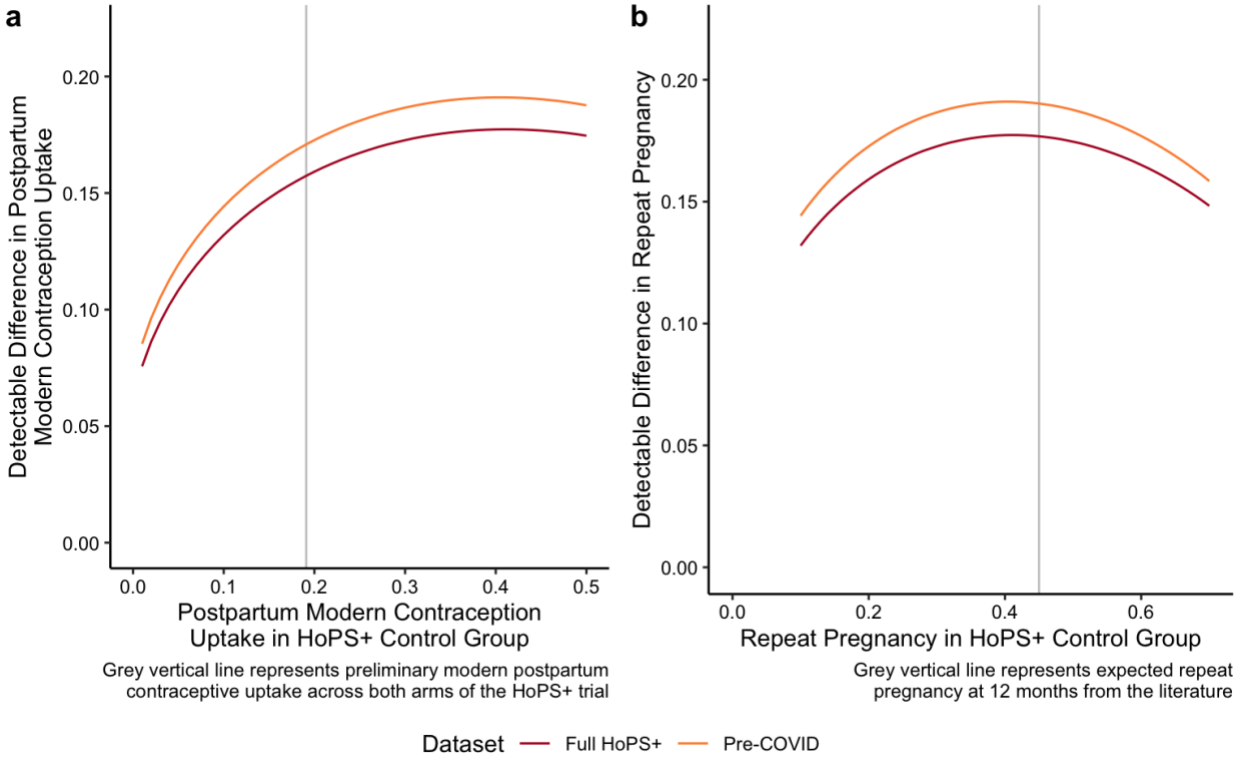
Figure 4. Detectable Difference in Postpartum Modern Contraceptive Uptake and Repeat Pregnancy



2.4.2 Power Calculation Aim 2 COVID-19 Sensitivity Analysis: Due to anticipated COVID-19 HoPS+ disruptions (at the time of my proposal defense all I knew was that participants would no longer receive visits from expert peer couples as of March 26, 2020), I planned a sensitivity analysis where I excluded all those who did not get the opportunity to complete all nine expert peer couple counseling sessions. This limited my

sample size to those recruited before April 26, 2019 (11 months before HoPS+ changed due to COVID-19 to allow ample time for scheduling difficulties that may have delayed the start or end of expert peer support visits). This included 643 individuals across 24 sites and impacted the power curves from above as shown in **Figure 5** for postpartum modern contraceptive uptake and repeat pregnancy as compared to the full HoPS+ trial with 80% power. Fortunately, while the detectable difference increased with a lower sample size, the detectable difference still appeared inside the realm of possibility, especially if there was low postpartum modern contraceptive uptake in the control group.

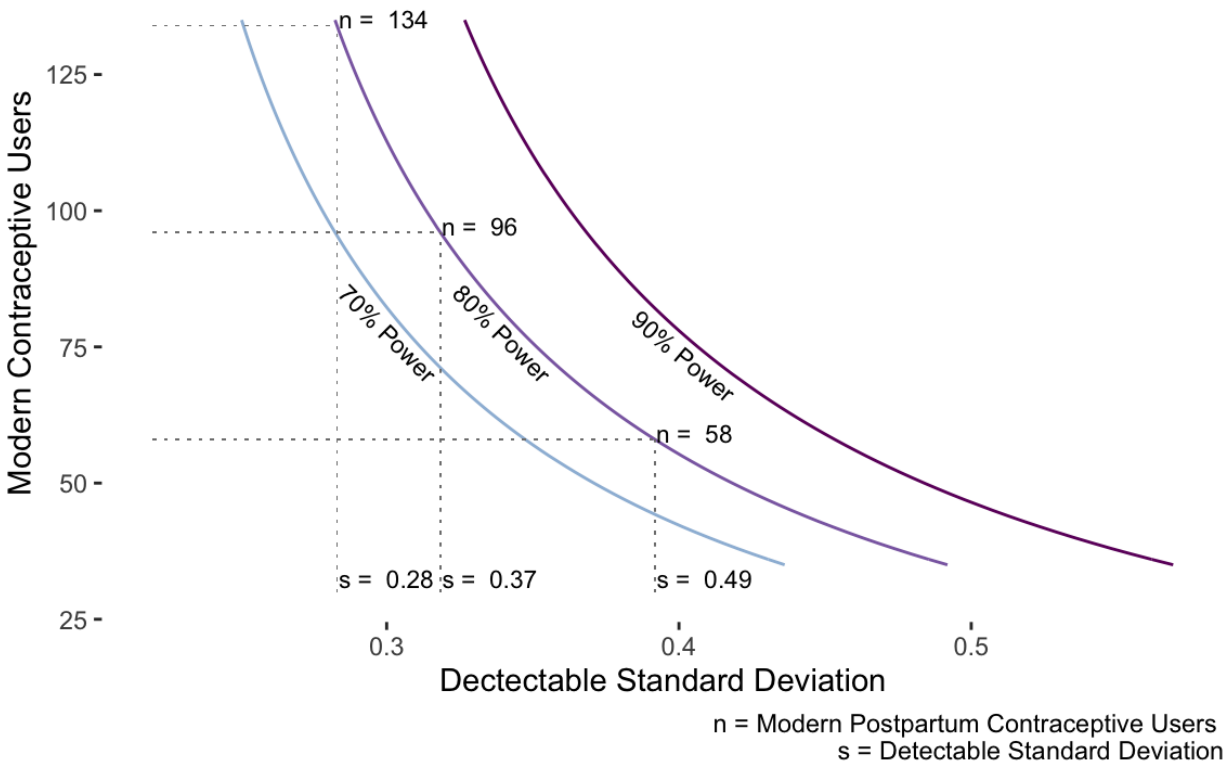
Figure 5. Detectable Difference with 80% Power in Postpartum Modern Contraceptive Uptake and Repeat Pregnancy among HoPS+ Participants Pre-COVID and with Full Recruitment



2.4.3 Power Calculation for Aim 3: To simplify the power calculation for Aim 3, I treated the outcome of interest – modern postpartum contraceptive uptake – as the "exposure"

and the exposure of interest – intervention fidelity as measured by number of counseling and skills and peer support sessions attended among female participants (**Aim 3a**) and male participants (**Aim 3b**) – as the "outcome". A simulation (n = 1,000) comparing a logistic model with a binary outcome "y" and continuous exposure "x" to a Wilcoxon Rank Sum Test with the binary exposure "y" and a continuous outcome "x" has highly correlated p-values (>0.98). It was therefore reasonable to assess power with a two-sample t-test, where I calculated, with 70, 80, and 90% power, the detectable standard deviation in intervention fidelity (**Aim 3a**) or prenatal visit attendance (**Aim 3b**) (**Figure 6**).[90] For example, if 96 women were to use modern contraception, I would have 80% power to detect a standard deviation of 0.37 or greater in the exposure – intervention fidelity in Aim 3a and prenatal visit attendance in Aim 3b – associated with an increased probability of modern postpartum contraceptive uptake.

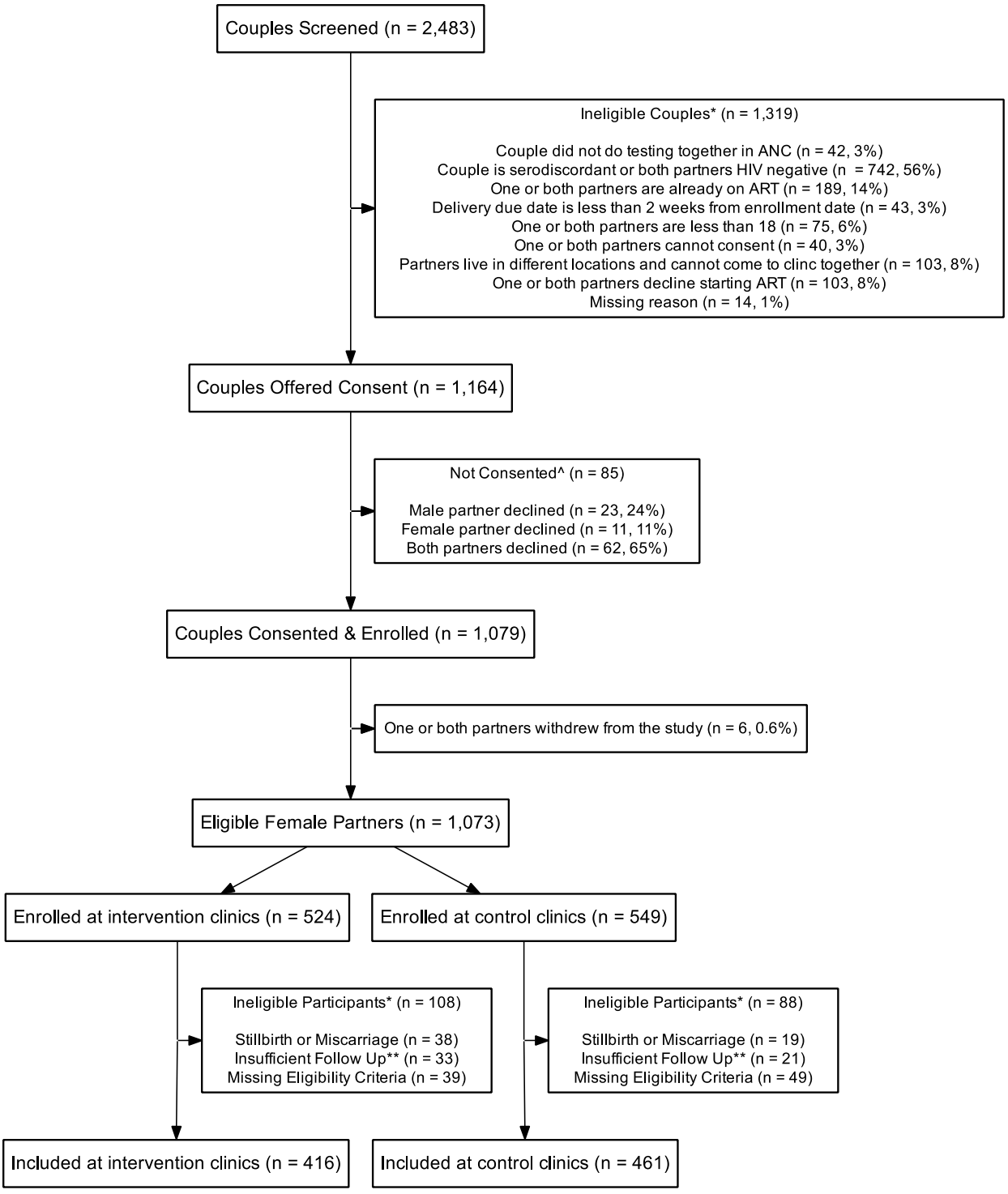
Figure 6. Detectable Standard Deviation for Aim 3



2.5 Study Enrollment and Baseline Data

HoPS+ study enrollment is presented in **Figure 7**. Of the 2,483 couples approached, 1,319 were ineligible. The majority of the 1,319 ineligible screened couples included a partner without HIV or both partners without HIV (n = 742, 56%). Of the 1,164 eligible couples, 1,079 were consented. The final baseline HoPS+ cohort included 525 couples at intervention clinics and 554 couples at control clinics. After the exclusion of participants without live birth (n = 58, 5.4%), without delivery at least a year before data collection (November 30, 2020, n = 54, 5%), and with missing inclusion criteria (n = 88, 8.2% – participants could be ineligible for more than one reason), the final study population for this dissertation included 416 female HoPS+ participants at intervention clinics and 461 at control clinics, for a total study population of 877 individuals.

Figure 7. HoPS+ Study Enrollment and Dissertation Eligibility



*Could be ineligible for more than one reason
^Some couples were recorded as not consented for more than one reason
**Delivery less than 1 year before November 30, 2021
ANC: antenatal care
ART: antiretroviral therapy

Complete HoPS+ baseline data shows steady enrollment over the study years and a median age of 23 (Interquartile Range (IQR) 20-28 in the control group, 20-27 in the intervention group) (**Table 2**). Almost half identify as legally single – but in a long-term relationship with their partner – and approximately one third identify as single – no long-term relationship with their partner. A majority report fewer than seven years of formal education (with more participants with no education in the control group 25.2% versus 17.8%) and work as farmers (with more participants in the control group working as farmers and more participants in the intervention group identifying as domestic workers). While female participants in the intervention arm report higher perceived community stigma (median 20 (IQR 12-30) versus 13 (6-23) in the control arm), other psychometric subscales are within 2-3 points across groups. Participants in both groups (~80%) where characterized as WHO HIV Clinical Stage I (the least sick) and had similar median body masses indices.

Table 2. Baseline HoPS+ demographic, psychometric, and clinical data

	Control (n = 461)	Intervention (n = 416)
Enrollment Year		
2017	14 (3.0%)	18 (4.3%)
2018	214 (46.4%)	171 (41.1%)
2019	146 (31.7%)	150 (36.1%)
2020	87 (18.9%)	77 (18.5%)
Age (years)		
Median [Q1, Q3]	23.0 [20.0, 28.0]	23.0 [20.0, 27.0]
Missing	0 (0%)	0 (0%)
District		
Pebane	101 (21.9%)	113 (27.2%)
Inhassunge	149 (32.3%)	24 (5.8%)
Namacurra	93 (20.2%)	64 (15.4%)
Mocubela	85 (18.4%)	52 (12.5%)
Maganja da Costa	0 (0%)	89 (21.4%)
Gilé	33 (7.2%)	57 (13.7%)
Quelimane	0 (0%)	17 (4.1%)
Relationship Status		
Living Together	225 (48.8%)	217 (52.2%)
Single	150 (32.5%)	129 (31.0%)
Married	86 (18.7%)	70 (16.8%)
Missing	0 (0%)	0 (0.0%)
Education		
None	116 (25.2%)	74 (17.8%)
Some Primary School (Grades 1-7)	267 (57.9%)	276 (66.3%)
Completed Primary School (Grade 7)	31 (6.7%)	22 (5.3%)
Some Secondary School (Grades 8-10)	28 (6.1%)	29 (7.0%)
Completed Secondary School (Grade 10)	11 (2.4%)	10 (2.4%)
College/Higher Education	8 (1.7%)	5 (1.2%)
Missing	0 (0%)	0 (0%)
Occupation		
Farmer	314 (68.1%)	218 (52.4%)
Domestic	135 (29.3%)	191 (45.9%)
Trader	3 (0.7%)	3 (0.7%)
Fisher	0 (0%)	0 (0%)
Other	7 (1.5%)	4 (1.0%)
Missing	2 (0.4%)	0 (0%)

Perceived Community Stigma		
Median [Q1, Q3]	13.0 [6.00, 23.0]	20.0 [12.0, 30.0]
Missing	43 (9.3%)	103 (24.8%)
Patient Felt/Experienced Stigma		
Median [Q1, Q3]	12.0 [8.00, 14.0]	13.0 [10.0, 14.0]
Missing	30 (6.5%)	66 (15.9%)
Physician Trust		
Median [Q1, Q3]	34.0 [30.0, 37.0]	36.0 [32.0, 39.0]
Missing	65 (14.1%)	104 (25.0%)
Cognitive Empathy		
Median [Q1, Q3]	19.0 [13.0, 22.0]	20.0 [14.0, 24.0]
Missing	60 (13.0%)	137 (32.9%)
Affective Empathy		
Median [Q1, Q3]	9.00 [5.00, 14.0]	12.0 [9.00, 16.0]
Missing	57 (12.4%)	135 (32.5%)
Perceived Support		
Median [Q1, Q3]	25.0 [22.0, 27.0]	27.0 [24.0, 28.0]
Missing	26 (5.6%)	28 (6.7%)
Need for Support		
Median [Q1, Q3]	29.0 [27.0, 31.0]	30.0 [28.0, 32.0]
Missing	36 (7.8%)	37 (8.9%)
HIV Knowledge (0-27)		
Median [Q1, Q3]	18.0 [15.0, 22.0]	15.0 [12.0, 19.0]
Missing	81 (17.6%)	196 (47.1%)
Patient Health Questionaire-9		
Median [Q1, Q3]	2.00 [0, 5.00]	3.00 [0, 6.00]
Missing	88 (19.1%)	70 (16.8%)
WHO HIV Clinical Stage		
I	373 (80.9%)	338 (81.3%)
II	33 (7.2%)	37 (8.9%)
III	9 (2.0%)	6 (1.4%)
IV	0 (0%)	1 (0.2%)
Missing	46 (10.0%)	34 (8.2%)
Body Mass Index (kg/m^2)		
Median [Q1, Q3]	21.5 [19.8, 23.3]	21.9 [20.1, 23.5]
Missing	50 (10.8%)	46 (11.1%)

Q1: first quartile
Q3: third quartile

3. Specific Aim 1: Qualitative analysis of contraceptive use among HoPS+ couples.

In light of the social, cultural, economic, and health system factors that affect modern contraceptive uptake in Mozambique,[42–44,48,49,51,55,61,91–94] a qualitative assessment of couples was necessary to comprehensively characterize how pregnant people and their partners weighed various factors and made the decision whether or not to use modern contraception in the postpartum period.

3.1 Approach to Aim 1: Develop a thematic map within the information, motivation, and behavior model,[84,85] through inductive and deductive coding, that frames perceptions of, attitudes towards, and experiences with modern contraceptive use among seroconcordant couples with HIV in HoPS+.

The HoPS+ trial recruited, with our partner in Mozambique, *Friends in Global Health*, 38 female participants and 26 male participants from six of the 12 intervention sites to participate in in-depth qualitative interviews between 12 and 18 months. Interviews assessed each individual's experience with the intervention, healthcare costs-related to their participation in the trial, intervention fidelity and acceptability, and suggested improvements to couple-based services in the health facility and community. Prior to the start of the interview process, I created four qualitative questions intended to elicit perceptions of, attitudes towards, and experiences with contraceptive initiation to supplement the HoPS+ questions (**Table 3**).

Table 3. Initial Qualitative Probes

1)	What is the ideal number of children to have here in Zambézia? Why?
2)	How many children would you like to have? What are the most important reasons to have _ number of children?
3)	Was your last child planned? Did you and your partner talk about using contraceptives?
4)	Now that your baby has been born, how did you make the decision to use or not use postpartum contraception?
	a) Tell me about any discussions you and your partner had about using contraceptives?
	b) How, if at all, did your counseling sessions help you and your partner discuss using contraceptives?

The first 29 interviews were completed before COVID-19 led to a pause in interviews, which allowed me to do a preliminary analysis of the available data and update the questions to elicit more comprehensive information about perceptions of, attitudes towards, and experiences with modern contraceptive use among HoPS+ HIV-positive concordant couples. Several of the participants reported wanting as many children as possible, whereas others reported a set number of desired children, but very few went into detail about what motivated their decision or how they came to their decision (including their partner's involvement). A few of the interviewees also reported learning about the health benefits of spacing their pregnancies and others noted an improved relationship with their male partner because of the intervention. Given that there were additional interviews planned, I took the following steps to improve data quality in subsequent interviews in line with the iterative nature of qualitative data analysis:[68]

1) Checked in with HoPS+ interviewers to learn about why they thought these questions were not generating detailed responses.

2) Changed question four in **Table 3** to the following: “Are you currently doing something to prevent pregnancy?” This formulation of the question was more direct and therefore improved the quality of participant responses (modified question in **Table 4**).
3) Added the following sub-question “c)” to question four in **Table 4**: “When would you like to have your next child?” as another probe at why or why not a couple was using modern postpartum contraception.

Table 4. Updated Qualitative Probes

1)	What is the ideal number of children to have here in Zambézia? Why?
2)	How many children would you like to have? What are the most important reasons to have _ number of children?
3)	Was your last child planned? Did you and your partner talk about using contraceptives?
4)	**Are you currently doing something to prevent pregnancy?**
	a) Tell me about any discussions you and your partner had about using contraceptives?
	b) How, if at all, did your counseling sessions help you and your partner discuss using contraceptives?
	c) **When would you like to have your next child?**

Boldface indicates an updated question

3.1.1 Sample Size Calculation: Interviews with 25 female and 25 male participants from six different clinics was estimated to ensure data saturation – defined as the point where no new information is gained from additional data collection – for contraceptive topics in this population.[95] This aligned with our team’s experience working in Zambézia Province. However, I analyzed the interviews after they were completed due to the delay from transcribing and translating the interviews. Therefore, although the

interviews reached data saturation after 50 interviews, I also analyzed the remaining interviews.

3.1.2 Population Selection: Couples enrolled in the HoPS+ trial at six of the 12 intervention sites were randomly selected using a randomly generated priority sampling list until three to five couples were selected from three of the intervention sites with the largest patient population and three of the intervention sites with the smallest patient population. This process resulted in in-depth qualitative information from 38 female participants and 26 male participants from six clinics.

3.1.3 Interviews: Trained study personnel conducted in-depth qualitative interviews with each partner separately. Interviews occurred in a private space at the health facility, the couples' home, or another location agreed upon by the participant and study staff. Interviews were administered in the participants' preferred language.

3.1.4 Cognitive Biases: An important component of qualitative analyses is recognizing how one's own biases may impact data interpretation.[68] In this case, I was predisposed to agree with participants who suggested that they were using contraception to maintain control over their fertility and disagree with those with different opinions. These different opinions may have been secondary to religious preferences, sociocultural norms, colonial and post-colonial governments' use of contraception as a means of subjugating people,[34–38,96] unethical HIV/AIDS and cancer clinical trials,[97,98] or some combination of all of the above. I was further predisposed to value each of these drivers of potential aversion to contraceptive use differently, which is unfair given that it is not my decision. In general, I believe that contraceptives (and abortion care – which is related but not addressed directly in this analysis) should be freely available and that people should

have the option to choose when and if they get pregnant (and what to do with each pregnancy) without interference. I recognize that this view may not align with that of HoPS+ participants, collaborators, or even readers. I was therefore cognizant of how my biases may manifest themselves when interpreting interview data and, more appropriately, other data in this dissertation. I do, however, hope these data provide valuable insights into how HoPS+ participants value family planning decisions and how the HoPS+ intervention impacts postpartum contraceptive decisions.

3.1.5 Main Analysis: I worked with Dr. Audet to develop the questions listed in **Table 3 & 4** to elicit perceptions of (information), attitudes towards (motivation), and experiences with (behavior) modern contraception among participants from in-depth qualitative interviews. Interviews were transcribed by trained study personal. Two bilingual study personnel then translated answers into Portuguese separately and iteratively checked each other's translations until they agreed. A third bilingual person mediated any disagreements. This process was repeated from Portuguese to English for the relevant questions (listed in **Tables 3 & 4**). I employed a thematic approach to identify and analyze themes in the data after repeated reading, using a combination of inductive coding and deductive codes based on findings from published literature.[99,100] The final codebook is presented in **Appendix 4**.

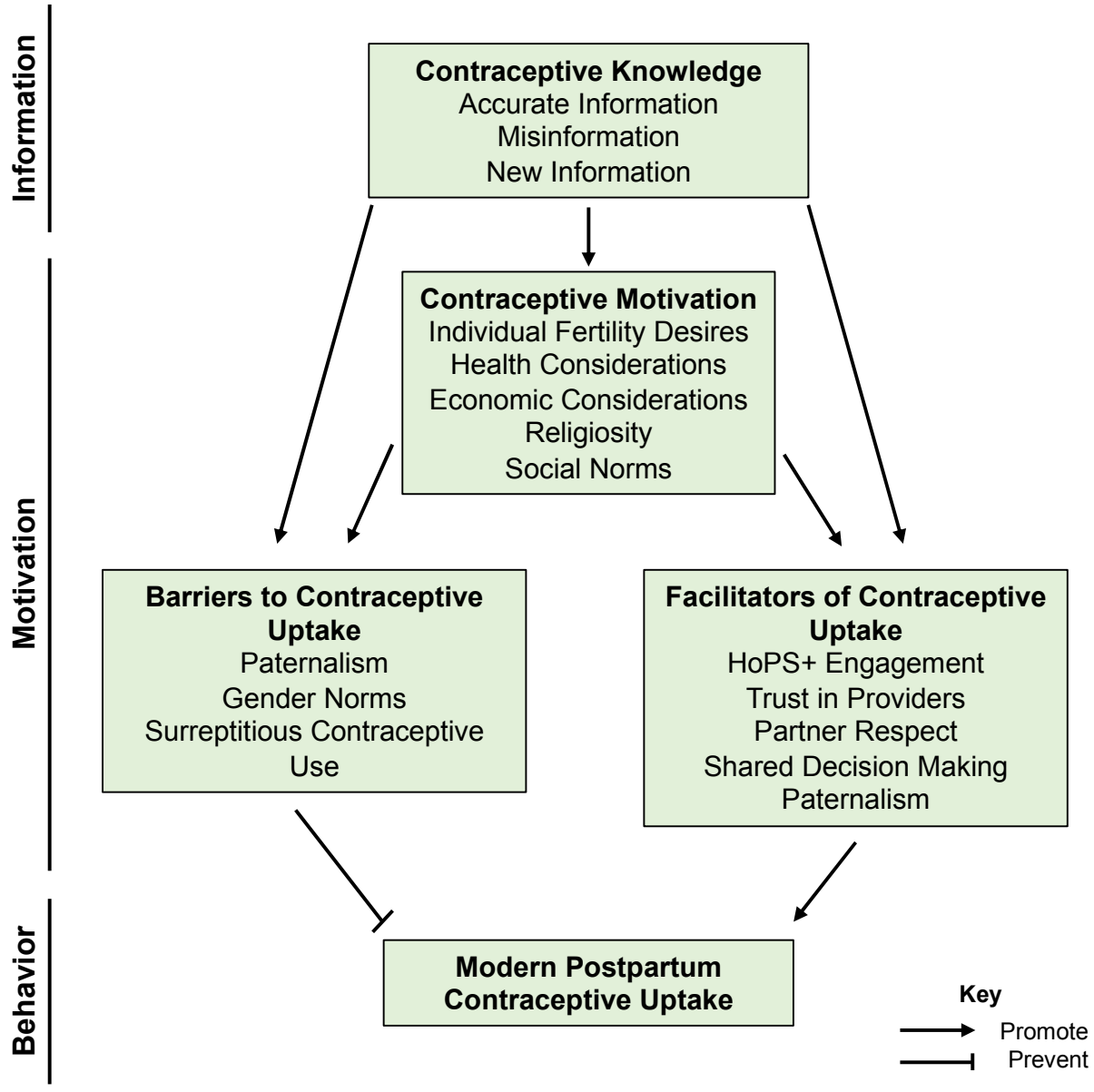
The questions in **Table 3 & 4** assessed how partner preferences were (or were not) communicated postpartum and important considerations that ultimately influence contraceptive uptake. These questions also elicited how intervention-targeted shared decision making and communication skills impacted couples' contraceptive decision-making process. I used existing literature to predict themes and compare what the

HoPS+ trial participants express to the perceptions and attitudes presented in literature that assesses participants' perceptions and attitudes towards modern contraception in Mozambique and sub-Saharan Africa.[26,41–43,48–51,55,91,93,101] These data allowed me to supplement and modify the theoretical model guiding the study intervention – the Information, Motivation, and Behavior Model[84,85] – on modern postpartum contraceptive uptake in Mozambique and sub-Saharan Africa **(Figure 8)**.[50] The information, motivation, and behavior model posits that information about risk-reduction, motivation to reduce risky behaviors, and behavioral skills, which are mutually reinforcing, drive risk-reduction behaviors and lead to favorable outcomes.[50]

I worked with Dr. Audet to generate codes and highlight themes by collating codes across the data set and reviewing themes to develop a thematic map (e.g. the relationship between relationship support and uptake of contraceptives) (**Appendix 4**, **Figure 8**). We identified 14 deductive codes and three inductive codes across five themes.[26,41–43,48–51,55,91,93,101] We used MAXQDA2020® software to ensure consistency across coding and analysis. The final coding framework had at least 85% agreement between two coders without the need for further discussion – although we did discuss divergent codes and mutually agreed on the best final option. The combination of HoPS+ trial participants' answers and the modified framework allowed me to assess **Hypothesis 1: women's perceptions of, attitudes towards, and experiences with modern contraceptive uptake would be influenced by their male partner, their knowledge, their comfort discussing contraceptive use with their partner, and their fertility intentions.** I found that the *Contraceptive Knowledge* theme corresponded to the *Information* theme, *Contraceptive Motivation*, *Barrier to*

Contraceptive Uptake, and *Facilitators of Contraceptive Uptake* corresponded to the *Motivation* theme, and *Support for Postpartum Contraceptive Uptake* and *Modern Postpartum Contraceptive Uptake* corresponded to the *Behavior* theme in the Information, Motivation, and Behavior Model (**Figure 8**).

Figure 8. Framework of Modern Postpartum Contraceptive Uptake



3.2 Results

The baseline demographic, psychometric, and clinical characteristics of the 64 interviewed participants are presented in **Table 5**. Female participants were evenly recruited before and after the COVID-19-induced interview pause, whereas more male participants were recruited afterwards (57.7% versus 42.3%). Female interviewees were younger (median age 22.5 years, interquartile range [IQR] 20-26.8 years) than male interviewees (27.5 years, IQR 25.3-31.5 years); and more likely do describe their relationship status as "single" (50% versus 34.6%), with very few interviewees of either sex describing their relationship status as married. Female interviewees also had less education than males and were more likely to work as farmers (60.5% versus 30.8%). Female and male interviewees had very similar median scores across all psychometric instruments. Females, however, attended a greater percentage of couples' skills sessions (median 100%, IQR 83.3-100%) and peer support sessions (88.9%, IQR 77.8-100%) compared to males (66.7%, IQR 50-83.3% and 66.7%, IQR 55.6-86.1% respectively).

Table 5. Baseline HoPS+ demographic, psychometric, and clinical data among qualitative interviewees

	Female (n = 38)	Male (n = 26)
Enrollment Year		
2018	15 (39.5%)	9 (34.6%)
2019	5 (13.2%)	4 (15.4%)
2020	18 (47.4%)	13 (50.0%)
Recruitment Relative to COVID-19 Pause		
Before	18 (47.4%)	11 (42.3%)
Afterwards	20 (52.6%)	15 (57.7%)
Age (years)		
Median [Q1, Q3]	22.5 [20.0, 26.8]	27.5 [25.3, 31.5]
District		
Pebane	5 (13.2%)	4 (15.4%)
Inhassunge	7 (18.4%)	3 (11.5%)

Mocubela	9 (23.7%)	7 (26.9%)
Maganja da Costa	10 (26.3%)	5 (19.2%)
Namacurra, Gilé, or Quelimane	7 (18.4%)	7 (26.9%)
Relationship Status		
Living Together	18 (47.4%)	16 (61.5%)
Single	19 (50.0%)	9 (34.6%)
Married	1 (2.6%)	1 (3.8%)
Education		
None	4 (10.5%)	0 (0%)
Some Primary School (Grades 1-7)	28 (73.7%)	13 (50.0%)
More Than Some Primary School	6 (15.8%)	13 (50.0%)
Occupation		
Farmer	23 (60.5%)	8 (30.8%)
Domestic	14 (36.8%)	—
Fisher	0 (0%)	9 (34.6%)
Other	1 (2.6%)	9 (34.6%)
Perceived Community Stigma		
Median [Q1, Q3]	15.0 [8.50, 23.5]	16.0 [10.0, 29.0]
Missing	14 (36.8%)	7 (26.9%)
Patient Felt/Experienced Stigma		
Median [Q1, Q3]	13.0 [9.00, 14.0]	12.0 [11.0, 15.0]
Missing	9 (23.7%)	4 (15.4%)
Physician Trust		
Median [Q1, Q3]	35.5 [32.0, 39.0]	35.5 [33.8, 39.0]
Missing	10 (26.3%)	6 (23.1%)
Cognitive Empathy		
Median [Q1, Q3]	24.0 [15.0, 25.0]	20.0 [15.0, 24.0]
Missing	19 (50.0%)	7 (26.9%)
Affective Empathy		
Median [Q1, Q3]	12.0 [8.50, 13.0]	11.0 [6.50, 12.0]
Missing	16 (42.1%)	10 (38.5%)
Perceived Support		
Median [Q1, Q3]	25.5 [21.0, 28.0]	25.5 [23.0, 28.0]
Missing	4 (10.5%)	2 (7.7%)
Needed Support		
Median [Q1, Q3]	28.5 [24.0, 32.0]	30.5 [24.8, 32.0]
Missing	8 (21.1%)	2 (7.7%)
HIV Knowledge (0-27)		
Median [Q1, Q3]	19.5 [17.0, 21.0]	18.0 [14.5, 19.5]
Missing	18 (47.4%)	11 (42.3%)

Patient Health Questionaire-9		
Median [Q1, Q3]	2.00 [0, 7.50]	1.50 [0, 3.25]
Missing	7 (18.4%)	6 (23.1%)
Proportion of Skills Sessions Attended		
Median [Q1, Q3]	1.00 [0.833, 1.00]	0.667 [0.500, 0.833]
Proportion of Peer Sessions Attended		
Median [Q1, Q3]	0.869 [0.778, 1.00]	0.667 [0.556, 0.861]
Using Modern Postpartum Contraception		
Yes	14 (36.8%)	—
No	14 (36.8%)	—
Missing	10 (26.3%)	—

Q1: first quartile
Q3: third quartile

While not all participants answered questions about their current number of children or desired number of children, answers ranged from zero to six current children and from three desired children to as many children as possible (with as high as 20 children in one participant), with most participants hoping for four children. Below, I will explore participant responses to each theme depicted in **Figure 8**. Each code is defined in greater detail in **Appendix 4**.

3.2.1 Contraceptive Knowledge: Contraceptive knowledge encompassed accurate information, misinformation, and new information about contraception gleaned from participating in the HoPS+ trial. While some participants shared information about the lactation amenorrhea contraceptive method, not all of it was strictly accurate. For example, while one participant correctly explained that “We haven’t weaned her so this helps the mother avoid pregnancy” (27-year-old male, Mocubela), however, he later reveals that the infant is 15 months old, beyond the timepoint at which exclusive breastfeeding is considered a highly efficacious contraceptive.[31,102] Several participants

shared the importance of birth spacing to prevent deleterious maternal and infant outcomes, with one explaining:

> It helped because [the HoPS+ counselor] explained to me [about birth spacing], I went and advised my husband, and he accepted that actually the children are little. If you don't [wait] you won't be in good health, you should rest and let the children grow up, then let's have another child later (20-year-old female, Inhassunge).

Other participants applied this knowledge to practical developmental milestones, with one explaining, "After [the child is] walking, [you can] stop the [family] planning" (24-year-old male, Mocubela).

While participants frequently shared information about birth spacing – some even had vague plans to only have another child in a set number of years – very few shared any information they learned about different family planning options. One male participant expressed that, "we didn't know there were pills you could take to decrease the number of children" (36-year-old male, Quelimane). Another shared, "They told us we can use a condom when we have sex outside" (39-year-old male, Gilé).

3.2.2 Contraceptive Motivation: Contraceptive motivation encompassed participants' individual fertility desires, including how health, economic, and religious considerations influenced these desires, and participants' views of the social norms surrounding fertility in their district. In general, female participants expressed a desire to, as one bluntly put it, "rest first" (30-year-old female, Inhassunge) prior to future pregnancies. Other female participants commented on the physical stressors that accompany pregnancy, with one explaining, "I suffer a lot when I get pregnant" (26-year-old female, Namacurra) with another agreeing:

> When I get pregnant my heart starts hurting…That's why I won't be able to. I can't do any house chores; when I realize I'm pregnant I don't do anything at home, I can't because my heart starts hurting (22-year-old female, Mocubela).

Beyond the physical, some reported other practical barriers to subsequent pregnancies, such as not having family members to help, or needing their children to be old enough to help with subsequent children (hence the desire to hold off for now). One female participant explained:

> It's a thought I've had for a long time because when you give birth to another child before the first is grown up, it's going to be your own suffering. Because a person will carry one [child] on their back as well as the pregnancy, then it's suffering. Now if one [child] is bigger, it will carry the other, and you as the mother will carry the bundle [of belongings] (38-year-female, Mocubela).

Some participants, however, were very excited to have additional children, with one female participant exclaiming, "maybe I would like twenty because it's good to have children at home" (20-year-old female, Gilé). One male participant was focused on his previous lived experience:

> The reason I want ten children, for example, my mother only had me, only me alone, yes, the brothers all died, the mother died, and just left with dad. So is the reason I ask and say at least ten (39-year-old male, Gilé).

Another focused on what children could provide him later in life, explaining, "When someone has six children, if there's no bad luck, you might get a few that will help you when they're grown up" (23-year-old male, Pebane). A few participants also reported that their newfound good health, after starting antiretroviral therapy for their HIV, stimulated thoughts about additional children. One male participant summarized, "I feel like I have good health, maybe I will think about having more children" (23-year-old male, Mocubela).

Several participants were also very cognizant of their economic situation and how it impacted their fertility desires. One male participant explained, “I used to think I could have a maximum of three or four. Because here in Mozambique, to have nine or ten children, poverty will add to poverty” (28-year-old male, Gilé). While some participants agreed, such as a female participant who said, “even having four in the [difficult economic] times we’re living in, I don’t know…” (27-year-old, Inhassunge), other participants disagreed, suggesting that additional children could help with wealth generation. One male participant elaborated, with a caveat:

> Oh you get so many riches [with more children] because there goes a pair of pants and a t-shirt, they will buy a bicycle and tell you, “Dad come to the farm with me.” Because all children can’t be poor. Even the poor one will come to his Dad’s house when Dad’s is not well and cut wood, cut grass, that’s the advantage of having a lot of children. But you need to be able to raise them (38-year-old male, Pebane).

Many participants also reported that their religious beliefs impacted their decision to have more children or use family planning. Several made similar statements to a female participant, who responded to a question about how many children she would like with the following: “Those who God wants to give us, according to his will” (19-year-old, Mocubela). A male participant elaborated that, “Since our religion says that planning is a sin, that’s why I say that [the number of children] will depend on the number God wants to give me” (27-year-old male, Mocubela).

Finally, participants reported that social norms suggested that people in their communities should have as many children as they would like (although there did not seem to be consistent expectations, even within the same study site). In addition to norms surrounding the number of children, there were expected tasks for the children. A female participant explained, “Girls pound flour [and] fetch water. Boys will also take you

to the hospital when you're sick [and] talk to the nurses, that's what a boy does" (20-year-old female, Mocubela). Another female participant elaborated:

> Because when the children are grown they can help you...When they are men and women: some go to the river, others gather firewood, and if they're grown they'll help their mother (25-year-old female, Pebane).

Participants generally agreed that people should have several children since they are likely to be differentially helpful as the parents age.

3.2.3 Barriers to Contraceptive Uptake: Barriers to contraceptive uptake included paternalism, gender norms, and the need for surreptitious contraceptive use. Several male participants noted, for example, that they should be in control of their female partners' fertility moving forwards. One explained, "I told her that she can't do planning alone without discussing with me" (19-year-old male, Quelimane). One female participant deferred speculating on how many children she might like, clarifying "I don't know, since my husband isn't here" (23-year-old female, Maganja da Costa). Another had a similar response, explaining "I don't know because he's not home…he would be able to tell me. But like, my wish alone is that I would like to rest" (27-year-old female, Inhassunge). This deferment to one's male partner aligned with the trend across all interviews that, in general, male participants were more expressive about their contraceptive attitudes and desire for additional children than female participants. One female participant felt the need to hide her family planning use from her male partner, explaining, "When I talk he won't listen. So I want to try to 'steal' [take contraceptives] by myself" (30-year-old female, Inhassunge). A male partner also expressed surprise when his partner started family planning without his input. He,

however, was open to it, reporting, “She did it and when I found out about the idea, I liked it. She said she wanted to rest…I said alright” (22-year-old male, Mocubela).

3.2.4 Facilitators of Contraceptive Uptake: Despite certain barriers to contraceptive uptake, participants reported that components of the HoPS+ intervention helped them discuss, and come to decisions about, contraceptive use with their partners. These facilitators of contraceptive use included general HoPS+ engagement, trust in providers, respect between partners, and examples of shared decision-making principles. In certain situations, however, paternalism also facilitated contraceptive uptake. For example, one male participant reported, “we talked about [family planning] first and then we made this decision [to use it]” (23-year-old male, Maganja da Costa). He was contradicted by his partner, who admitted that her “husband forced me [to have an implant] …he’s the one who forced me” (18-year-old female, Maganja da Costa).

Most participants reported good engagement with HoPS+ activities and personnel. Engagement with the HoPS+ intervention also facilitated respect and shared decision making among participants. Both the female and male participant from the same couple (26-year-old female & 26-year-old male, Namacurra) separately agreed that they engaged in shared decision making to reach a “consensus” about family planning. Another participant described how the couple’s counselor encouraged him to engage in shared decision making with his partner (and provided an example of them doing so):

> When we went to the hospital she told us about [family] planning, and she [the couple’s counselor] said, “go home, talk to each other and when you come back next time tell me what you think about the subject.” We talked, so when it’s time we are going to do it [family planning] (27-year-old male, Mocubela).

Participants also reported that the HoPS+ study personnel generated a great degree of trust, which facilitated both antiretroviral therapy adherence and an openness to use

postpartum contraceptives. One female participant summarized, “If they [the HoPS+ peer support counselor] come to my house and tell me something, I will also do that because they told me to” (25-year-old female, Gilé). One female participant gave an example of a mistrust in health providers, perhaps due to underlying HIV-related stigma:

> Our misunderstanding is not because our HIV positive status, it’s because of the way he [my partner] is. He refused to get the antiretroviral treatment, claiming he can’t stand taking the pills. But when he got tested it was positive. He said he will only do the treatment when he’s sick and in a critical state (30-year-old female, Pebane).

A female participant also reported that the skills she learned through HoPS+ were generalizable to other situations, explaining, “when one of us makes a mistake, we have a good conversation” (20-year-old female, Inhassunge). A male participant continued, “There was no respect there [with my wife before the HoPS+ intervention] …but now there is respect” (26-year-old female, Maganja da Costa). A different male participant summarized:

> My relationship with my wife really did change…we didn’t understand each other before, we would each accuse the other. So then this phase arrived, we are established, no one accuses the other, everything is normal, it’s normal. We live without any problems, no arguments, we are able to talk and get over problems (34-year-old male, Maganja da Costa).

A female participant was also complementary of what her and her partner learned through the HoPS+ intervention, “We have been happier because now we have these ideas that they give us both when we are in the hospital" (21-year-old female, Gilé).

3.2.5 Modern Postpartum Contraceptive Uptake: Finally, some participants disclosed their current postpartum contraceptive use status. For example, one couple independently agreed that the female partner was using an implant to avoid unintended pregnancies (18-year-old female & 23-year-old male, Maganja Da Costa).

3.3 Discussion

The 64 interviewed HoPS+ participants perspectives, particularly with the inclusion of male partners, add to the literature on contributors to postpartum contraceptive uptake among couples with HIV. For example, Agadjanian and Hayford (2016) postulated that improved access to antiretroviral therapy in southern Mozambique tempered a "now-or-never" approach to childrearing in rural Mozambique among people with HIV.[43,103] Specifically, people with HIV in the region had previously worried that, given their impending death prior to the widespread availability of antiretroviral therapy, they needed to have as many children as possible as soon as possible (or not have any children).[103] Female and male participants expressed support for this attitude shift towards more planned and spaced subsequent pregnancies. In addition to highlighting their own improved health on antiretroviral therapy, they were optimistic about preventing HIV acquisition in their children. Additionally, there is evidence that religious beliefs are essential contributors to family planning decisions in Mozambique,[42] which was also evident in these interviews in both female and male participants.

Participants of both sexes also supported the principle of "resting" between pregnancies to make sure they and their families are healthy for subsequent pregnancies. This aligns with the principle of "healthy timing and spacing of pregnancies" which aims to promote 24 months between pregnancies, per the WHO's recommendations,[12] in programs that provide reproductive health services.[104] The idea of healthy timing and spacing was implemented across USAID and other United States government programs starting in the 1990s, including the President's Emergency Plan for AIDS Relief (PEPFAR) in the 2000s, because it was explicitly exempted from the Mexico City Policy – which originally

prevented foreign organizations from using government funding to perform or promote abortion services and, under President Trump, was expanded to restrict the use of any development programs, PEPFAR included, for the same purpose.[104,105] This is highly relevant given that, since the early 2000s, the United States has given more official development assistance than other high income countries (albeit, a lower share of their gross domestic product is directed towards development assistance).[106] While I do not have data from before healthy timing and spacing's widespread incorporation into global reproductive health programming, the HoPS+ participants have certainly picked up on the importance of birth spacing, which suggests that the core messaging – on the health benefits of birth spacing – has been rather effective. However, these data also raise pressing questions about intervention planning and contraceptive knowledge that require further examination.

Specifically, this study elevates the importance of how to include female and male partners when intervening on contraceptive uptake, particularly given the gendered perspectives evident in this analysis. Qualitative studies of couples in Mozambique have demonstrated that female and male partners play different roles to prevent the acquisition and spread of HIV,[107] which also extends to contraceptive decision-making.[45] Previous work supports that improved spousal communication and improved shared decision making skills, such as those gained from HoPS+, may positively influence contraceptive uptake in SSA.[50,101] Importantly, however, we also found cases where female partners were forced into using postpartum contraceptives, felt the need to use contraceptives without their partners' knowledge, or reported that their male partners made reproductive decisions for them. This suggests that communication and

shared decision making strategies are limited, particularly in cases with partners that range from disinterested to abusive, which may inadvertently decrease access to care and lead to worse pregnancy outcomes.[108] This complicates intervention planning for pregnant people with partners intent on controlling their reproductive decision making.[109] Interventions should therefore center pregnant partners and allow them to titrate the level of non-pregnant partner involvement based on their needs. Interventions will have the strike the right balance between promoting agency (in both partner involvement and reproductive decisions) and creating broadly applicable programs that do not impose a one-size fits all approach that may lead to worse outcomes for some participants.

Participants also frequently reported that they were preventing future pregnancies via continued breastfeeding. This is an example of the lactational amenorrhea method (LAM), where breastfeeding disrupts the pulsatile secretion of luteinizing hormone and thereby reduces the likelihood of ovulation.[110,111] Consensus guidelines on LAM, which suggest high efficacy (98%) at preventing pregnancy for the first six months of the postpartum period, however, require exclusive breastfeeding, amenorrhea (no menstrual periods), and an infant less than six months old.[102] These guidelines, which are still cited by the Centers for Disease Control and Prevention,[112] were written in 1989 and updated in 1992 based on primarily small observational studies with no significant data collection since their publication.[102,111] This is further complicated by the fact that these small studies suggested that if postpartum people were no longer exclusively breastfeeding or resumed menstruating – which nutritional status did not seem to impact – the efficacy of LAM decreased significantly and quite quickly.[30,102,110,111,113]

Furthermore, while it is easy to assess breastfeeding frequency, the resumption of menses after pregnancy can be difficult to measure and may require serological testing (although proxies such as two consecutive days of bleeding after 56 days postpartum may provide some measurement flexibility). [30,102,110,111,113] New randomized trials would require using a safe and reliable reference method (such as an intrauterine device) and would likely not meet the clinical equipoise ethical requirement for follow up longer than 6 months without new, robust observational data suggesting efficacy similar to other modern contraceptive methods after six months (such as condoms or oral contraceptive pills). The HoPS+ participants, however, certainly report using LAM after six months delivery, so its efficacy after six months deserves further study. Observational cohorts that measure breastfeeding frequency and contraceptive use at various time points in the postpartum period may provide further insight into this question even in the absence of resumption of menses data.

Finally, while I had hoped the questions would elicit why participants were using particular methods, participants did not provide detailed information on why they were using one method over another – although contraceptive availability may have played a role. This information would help guide future interventions aimed at increasing highly efficacious contraceptive uptake. For example, some scholars have posited that injectable contraceptives are popular because they allow people seeking to prevent pregnancy to use a highly effective contraceptive method without the knowledge of their partner or family members.[114] They could also be popular because they only require a trip to the clinic for an injection every three months (which also is convenient for new parents taking their children for immunizations) rather than a daily pill or a device

insertion.[114] Given evidence that male partners make the reproductive health decisions in Mozambique for over a quarter of couples,[45] which some HoPS+ participants also suggested, more information on why individuals select specific contraceptive methods would be helpful and would require additional qualitative studies.

These results are also subject to several additional methodological limitations. HoPS+ participant perspectives may not be transferable to urban regions of Mozambique (or elsewhere in sub-Saharan Africa) due to different life experiences, fertility priorities, and religious beliefs in different regions. Additionally, by design, these interviews do not include individuals who did not attend HoPS+ intervention sessions. As such, these interviews did not provide insight into how to improve engagement in future behavioral interventions aimed at increasing postpartum contraceptive uptake. Furthermore, for the most part, participants did not provide examples of how the HoPS+ or the health system increased or decreased access to contraception, which would have provided additional information to guide future interventions. The general themes, however, aligned with other research in the field and were consistent among participants of both sexes. This will improve planning for future interventions aimed at increase postpartum contraceptive uptake in the region.

4. Specific Aim II: Quantify the impact of HoPS+ on modern postpartum contraceptive initiation and continuance, and repeat pregnancy

The HoPS+ trial was developed to assess the efficacy of male-partner involvement on maternal adherence to treatment and retention in HIV care, and maternal to infant HIV transmission.[69] It addresses contraception through counseling session discussion prompts during at least one of the six sessions and provides male partners with exposure to the importance of postpartum contraception during joint pre and post-natal visits. The HoPS+ protocol also required clinical data collection that allowed for directed secondary analyses.[69] **These data included records of contraceptive initiation and continuation (uptake) and repeat pregnancies in the medical record and on supplementary HoPS+ trial-related documents that allowed me to proceed with the proposed secondary analysis** (**Appendix 1**)**.** Study personnel collected data from participants at each study visit and store de-identified clinical outcomes, including postpartum contraceptive use and repeat pregnancy information, on a shared electronic data storage platform. Study personnel periodically checked internal data with medical record data for each HoPS+ participant to ensure data quality. Discrepancies were corrected and initiated a comprehensive review of medical records for each site with identified incorrect data.

4.1 Approach to Aim 2: Quantify the impact of HoPS+ on modern postpartum contraceptive initiation and continuance, and repeat pregnancy during the 12 months after live birth among women living with HIV.

This project used the HoPS+ trial (Vanderbilt IRBs FWA00005756, IRB00000475-7, and IRB00002125 and Mozambican Ministry of Health IRBs FWA00003139 and

IRB00002657) to quantify the effect of the HoPS+ intervention – male partner engagement in care, couples counseling sessions, and expert peer support couples – on modern postpartum contraceptive uptake and repeat pregnancy rate. All female participants included in the HoPS+ trial were included in this aim (1,073 female participants) except those who experienced a miscarriage, stillbirth, had not delivered at least 12 months prior to data collection from the medical record (November 30, 2021), had missing delivery date or delivery outcome data (n = 108, **Figure 7**), or those who withdrew from the study (or whose partner withdrew, n = 6). The final study population therefore included 416 women in the intervention group and 461 women in the control group (n = 877, **Figure 7**).

4.1.1 Hypotheses:

Aim 2a: I hypothesized that women in the intervention group would have a higher odds of modern postpartum contraception initiation and continuance and a lower hazard of repeat pregnancy after live birth than those in the control group.

4.1.2 Exposure: The primary exposure for **Aim 2a** was assignment to the intervention or standard of care group of the HoPS+ trial (dichotomous).

4.1.3 Primary Outcome: The primary outcome was defined *a priori* as postpartum modern contraceptive uptake,[31] defined as modern contraceptive initiation and/or continuation documented in the medical record **12 months from live birth** (dichotomous). This would assess sustained postpartum contraceptive use to adequately space births and prevent deleterious maternal and fetal outcomes associated with short inter-pregnancy intervals.[1,2] I also planned an *a priori* sensitivity analysis of recorded contraceptive use at any time (modern postpartum contraceptive

initiation only, dichotomous) in the postpartum period based on the medical record or HoPS+ trial-related documents. Although I considered modeling postpartum contraceptive use as a time-to-event outcome, since someone can start postpartum contraceptives and later discontinue them, the interpretation could become challenging and less meaningful. Unfortunately, the available outcome data were insufficient to assess my *a priori* primary outcome. Specifically, data were recorded on family planning use at each postpartum clinic visit. The medical record data, which only provided use of family planning at one time point, only included complete data on 27.7% of participants. Fortunately, HoPS+ study personnel reported data was complete for 73% of participants, although only 22.3% of participants had complete information on when (the date) they were or were not using postpartum contraceptives. While I am confident that those with missing contraceptive use dates had information recorded within 12 months of their delivery, it is impossible to know exactly when that information was recorded during that period (e.g., one week postpartum or 11 months postpartum). As such, I created a spreadsheet of participants (with new random identifiers to avoid reviewer bias) that included each participants' delivery date, 12 months from their delivery date, their contraceptive method and the date it was recorded in the medical record, and their contraceptive use, method, and the date it was recorded by HoPS+ study personnel. Erin Graves and I reviewed these spreadsheets independently to adjudicate whether each participant used family planning in the postpartum period. In cases where the medical record data and HoPS+ study personnel-recorded data did not agree, we prioritized the datapoint closest to 12 months from the delivery date in days or the data source with a date. In cases where HoPS+-recorded data and medical record data were

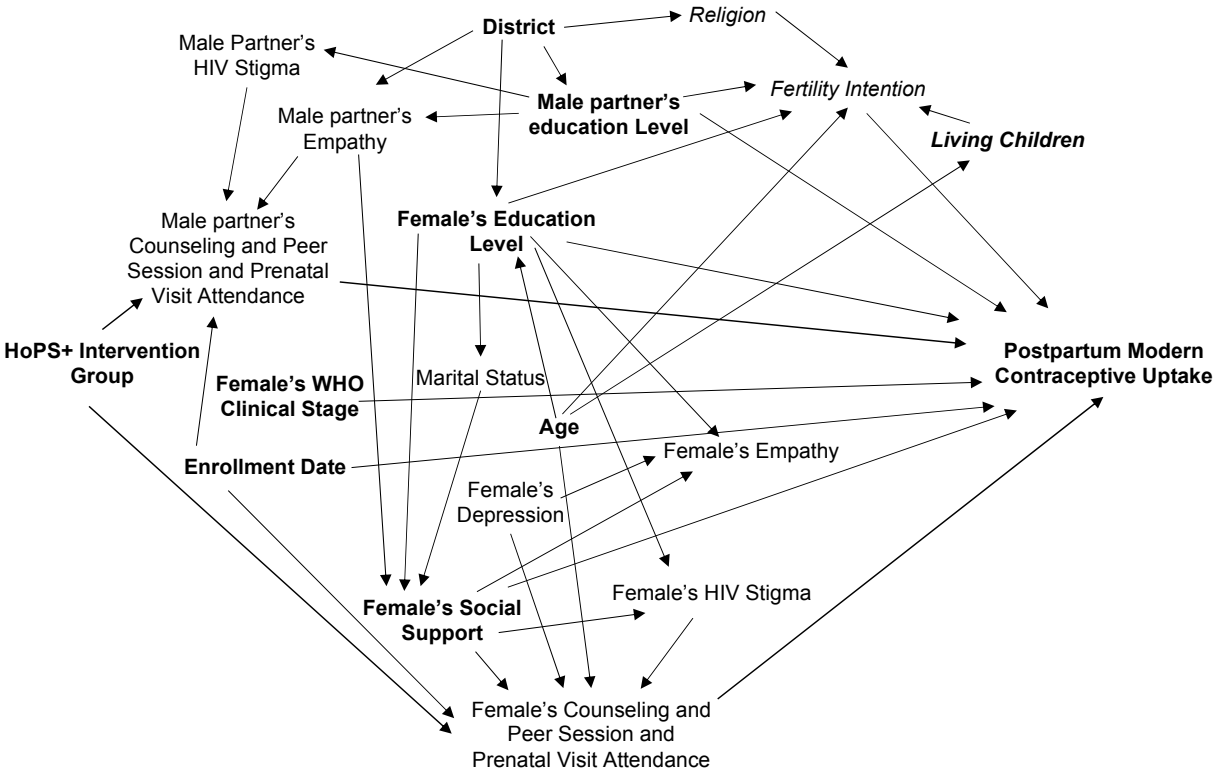
recorded on the same date and in conflict, we deferred to medical record data. In cases where contraceptive use was recorded prior to birth, these were classified as someone who did not use a contraceptive in the postpartum period. Ms. Graves and I disagreed in seven cases after the first pass and were able to resolve all the differences without additional input from Dr. Audet (our chosen tie breaker in cases of disagreement). The *post hoc* primary outcome was therefore updated to the somewhat clunky: **postpartum modern contraceptive use any time during the postpartum period**, with the datapoint closest to 12 months postpartum used in cases where HoPS+ study data conflicted with medical record data.

4.1.4 Secondary Outcome: The secondary outcome was defined *a priori* as repeat pregnancy, defined as a positive pregnancy test documented in the medical record **in the 12 months after a live birth** (time-to-event). Unfortunately, there was no information in the medical record on this secondary outcome and only one recorded repeat pregnancy within 12 months recorded the HoPS+ study data, which precluded my doing this analysis. If I expanded my timeframe to two years (24 months), there were still fewer than 20 recorded repeat pregnancies, which made it impossible to complete this analysis.

4.1.5 Confounders (Covariates): While exposure group assignment is cluster randomized, I created a directed acyclic graph (**Figure 9**) that suggested adjusting for the following baseline variables that were likely to be predictive of the outcome (available for participants in both arms of the trial; **bolded** in **Figure 9**): women's age (continuous), enrollment time (continuous days from first HoPS+ enrollment), male and female partner education (no education, some primary, completed primary, some

secondary, completed secondary, college/higher education), female partner World Health Organization HIV clinical stage (ordinal), district (Pebane, Inhassunge, Gilé, Quelimane, Mocubela, Namacurra, Maganja da Costa), and composite social support (continuous). I had also planned on controlling for number of living children (count); however, it was not available. Covariate adjustment in randomized trials simultaneously accommodates the impact of chance imbalance leading to residual confounding and increases statistical power when covariates are highly predictive of or of prognostic importance to the outcome of interest.[87–89] For a detailed overview of how and from where these covariates were collected, please see **Appendices 1** and **2**. Some covariates that are likely highly correlated with the outcome of interest (pre-pregnancy contraceptive use and current pregnancy intention) were not available in the HoPS+ trial dataset.

Figure 9. Directed Acyclic Graph for Aim 2

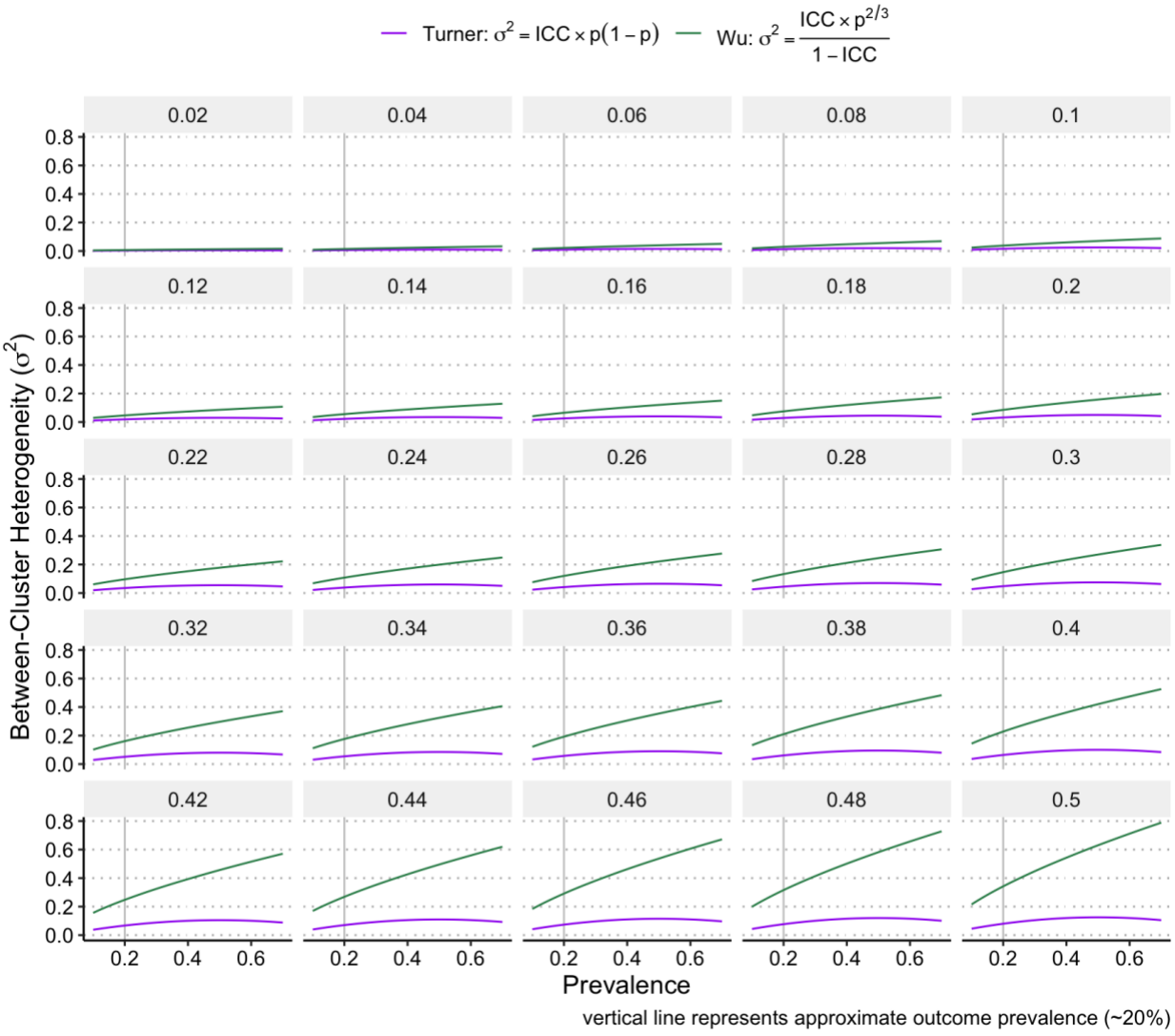


4.1.6 Statistical Analysis and Simulations: All analyses were completed in *R Statistical Software* (Version 4.1.0). The clustered nature of the data required special attention.[115–117] The "population-average" or marginal effect is more appropriate than the "cluster-specific" or conditional effect, however, Generalized Estimating Equations (GEE), a popular marginal model because of its semi-parametric estimating procedure and variance estimates robust to covariance structure misspecification, tends to underestimate variance when there are fewer than approximately 40 clusters without variance correction.[118–124] Marginalized Multilevel Models (MMM), another type of marginal model, use likelihood-based estimation and pair a marginal mean model with a model that describes within cluster dependence by conditioning on cluster-level random effects.[124–127] Both GEE and MMM appropriately result in an effect estimate (β_1) that

estimates the average effect of the HoPS+ intervention on modern contraceptive uptake, adjusted for covariates (β_n). Each covariate coefficient does not represent a causal effect for any particular covariate, since residual confounders likely exist that influence the relationship between each covariate and postpartum modern contraceptive uptake.[128]

To determine whether to use GEE with an exchangeable correlation structure (with or without a small sample variance correction) or MMM (with or without a small sample variance correction), I followed Bie et al.'s (2021) general protocol and simulated clustered binary outcomes using baseline HoPS+ data (except for clinical covariates, which were not available when I completed the simulations).[123,124,129–131] Recognizing that there several ways to estimate between-cluster heterogeneity (σ^2), I started by simulating expected σ^2 assuming intracluster correlations (ICC) between 0.01 and 0.50 by 0.02 and outcome prevalence (p) between 0.10 and 0.70 by 0.01 (**Figure 10**).

Figure 10. Calculated σ^2 Depending on Final HoPS+ Intracluster Correlation



These results informed 1000 simulations comparing bias, coverage, and standard errors between GEE (with and without the Mancl and DeRouen (MD) variance correction)[123] and MMM (with and without a degree of freedom (DOF) variance correction that scaled standard error estimates by a factor of $K / (K - p)$ where K is the number of clusters (24) and p is the number of model parameters).[124] Using baseline HoPS+ data, with continuous covariates standardized about their mean and standard deviations:

$$\frac{covariate - mean(covariate)}{sd(covariate)}$$

Clustered binary outcomes (by HoPS+ clinic) were either generated solely based on the intercept ($\alpha \in$ {-2, -1.5, -1}), which influenced outcome prevalence (approximately 12-30%), and HoPS+ intervention group (β_1 = 0.25) ("None") or the intervention group and all available continuous covariates (age, stigma, male empathy, female social support, and days from enrollment) ("Most"), with covariates randomly generated via $\beta_n \sim N(0, 0.15)$ each simulation.[131] This is because including categorical variables caused an error in calculating the Mancl and DeRouen small sample variance estimator for the GEE model in some iterations, dramatically slowing down the simulation.[123,130] Results from **Figure 10** informed setting between cluster heterogeneity $\sigma^2 \in$ {0.01, 0.05, 0.1, 0.2, 0.5}, recognizing that as σ^2 increases, participants within clusters are more similar to each other. Results from the simulation are presented in **Table 6** (when α = -1.5, which approximates an outcome proportion of 20% with "Most" covariates) and **Figures 11-13**.

Table 6. Simulated Bias, Standard Errors, and Coverage with "Most" Covariates (α = -1.5)

	Between Cluster Heterogeneity (σ^2)				
	0.01	0.05	0.1	0.2	0.5
Generalized Estimating Equations					
Bias (%)	-0.005	-0.004	-0.004	0.003	-0.002
	(-2.0)	(-1.7)	(-1.8)	(1.2)	(-1.0)
Standard Error Bias (%)	-3e13	-3e12	-1e13	-0.016	-0.007
	(-98.8)	(-91.1)	(-97.3)	(-8.9)	(-2.9)
Coverage	0.91	0.909	0.901	0.917	0.919
MD Standard Error Bias (%)	-3e13	-4e12	-1e13	0.009	0.023
	(-100)	(-100)	(-100)	(4.9)	(9.1)
MD Coverage	0.947	0.943	0.945	0.952	0.959
Marginalized Multilevel Model					
Bias (%)	-0.006	-0.005	-0.005	0.0003	0.001
	(-2.5)	(-2.0)	(-2.1)	(0.11)	(0.59)
Standard Error Bias (%)	0.003	-0.001	-0.001	-0.006	-0.004
	(1.9)	(-0.5)	(-0.4)	(-3.5)	(-1.7)
Coverage	0.949	0.95	0.948	0.941	0.932
DOF Standard Error Bias (%)	0.071	0.067	0.068	0.065	0.096
	(43.9)	(40.5)	(40.7)	(36.3)	(38.9)
DOF Coverage	0.997	0.989	0.996	0.991	0.989

1000 Simulations

MD: Mancl and DeRouen small sample correction

DOF: degree of freedom small sample correction

Standard Error Bias standardized to most extreme values

Figure 11. Percent Bias Across 1000 Simulations by Covariates and σ^2

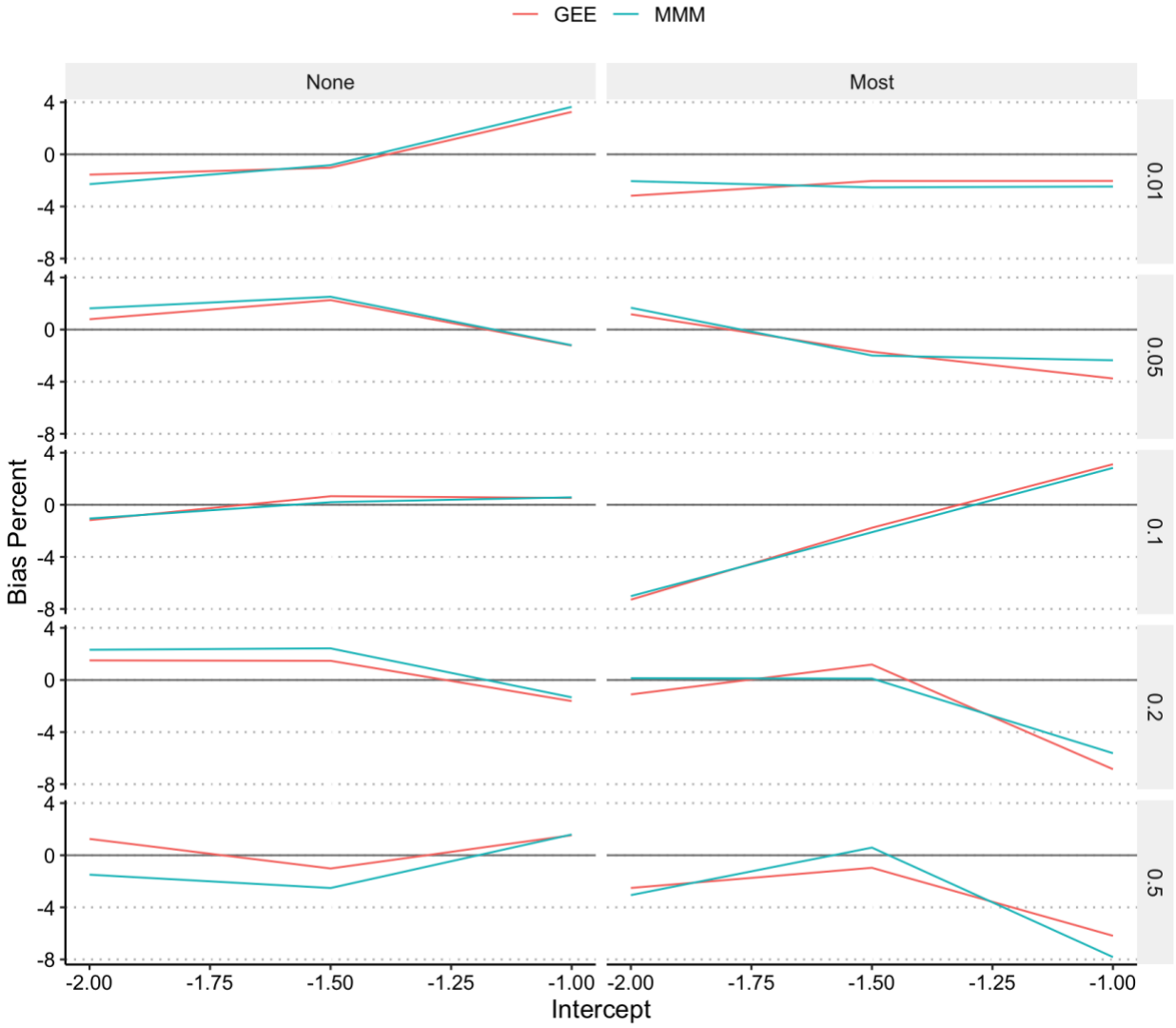


Figure 12. Percent Standard Error Across 1000 Simulations by Covariates and σ^2

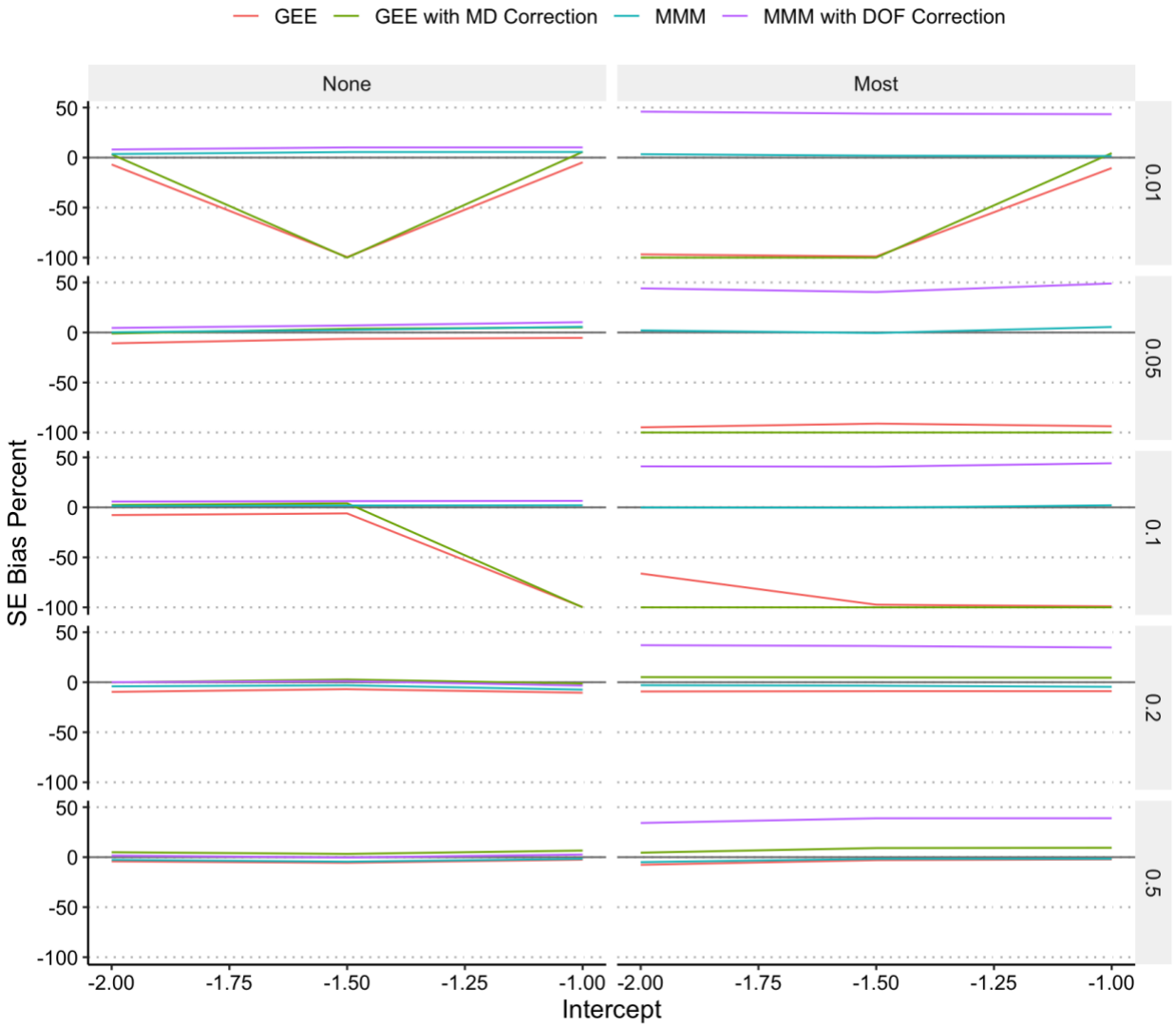
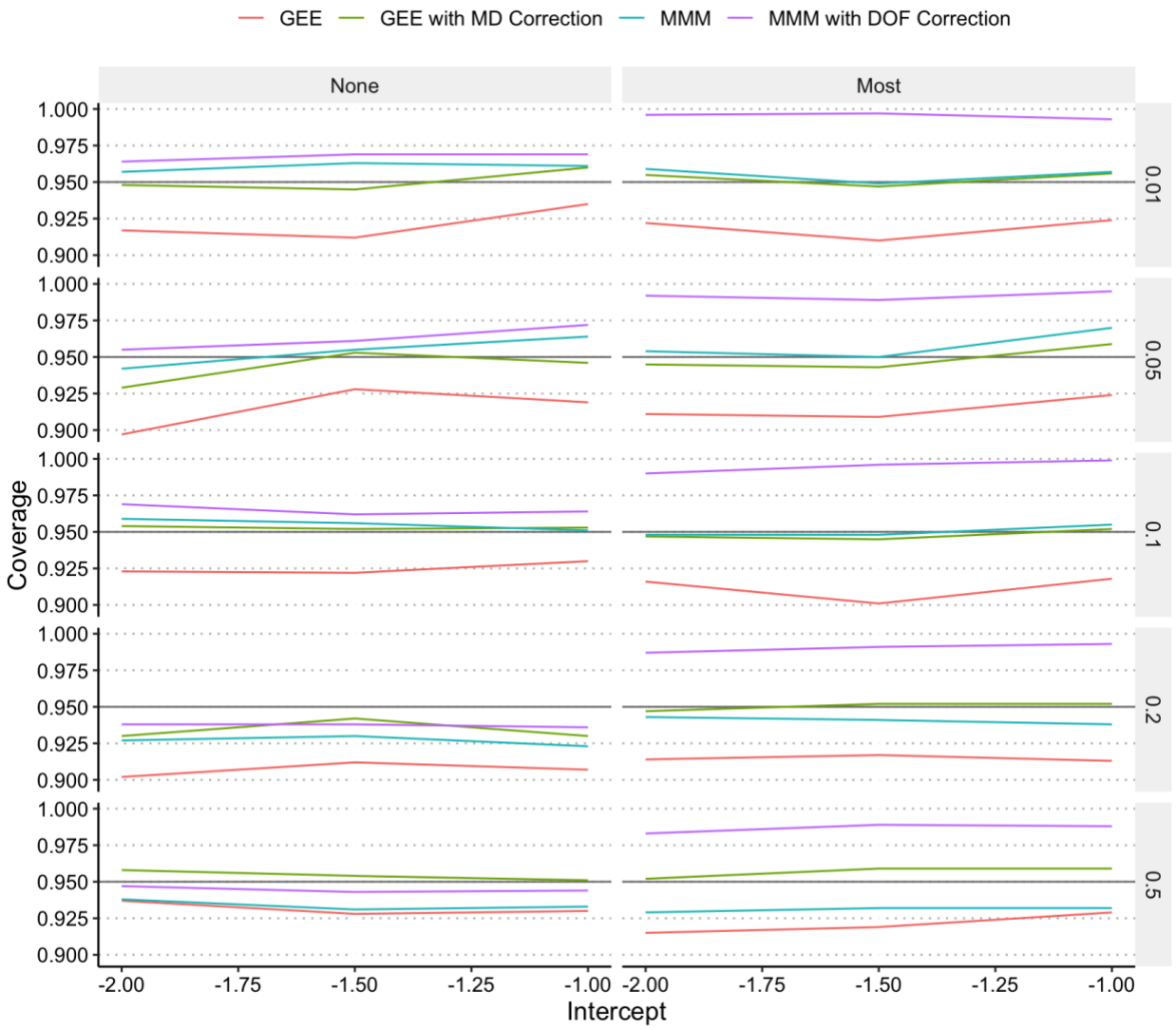


Figure 13. Coverage Across 1000 Simulations by Covariates and σ^2



Fortunately, bias was very similar regardless of whether I used an MMM or GEE model regardless of the number of covariates or σ^2 (**Figure 11**). Standard error bias, however, was uniformly high in the MMM with the DOF correction with any covariates, making it inappropriate (**Figure 12**), whereas MMM performed uniformly well across all scenarios. Standard error bias for both types of GEE models (with and without the MD correction) did not perform well when $\sigma^2 \in \{0.01, 0.05, 0.1\}$, but had favorable properties when $\sigma^2 \in \{0.2, 0.5\}$ (**Figure 12**). The MMM with DOF correction uniformly had the highest

coverage (which fits with its general overestimate of standard error bias) and the GEE without the MD correction uniformly had the lowest coverage, which left a decision between the regular MMM and the GEE with MD correction, which performed similarly when $\sigma^2 \in \{0.01, 0.05, 0.1\}$ (**Figure 13**). Since the GEE with MD correction had better coverage when $\sigma^2 \in \{0.2, 0.5\}$ and acceptable standard errors (**Figure 13**), I based my *a priori* analysis plan on σ^2, calculated from the "MMLB" package.[131] If $\sigma^2 < 0.2$, I planned to use MMM for my unadjusted, primary, complete case, likely case, and worst-case analyses and run a GEE with MD correction for a sensitivity analysis; however, if $\sigma^2 \geq 0.2$, I planned to use GEE with MD correction for my unadjusted, primary, complete case, likely case, and worst-case analysis and run an MMM for a sensitivity analysis (**Table 7**).

I tested the null hypothesis, H_0: $\beta_1 = 0$ and the final model included the covariates listed above, with some minor exceptions to allow models to run, described below. To avoid linearity assumptions and reduce residual confounding I included continuous covariates using restricted cubic splines with three knots.[88] This was an intent-to-treat analysis and I used multiple imputation that accounted for the clustered nature of the data to account for missing covariate and outcome data.[132–135] Multiple imputation can produce unbiased effect estimates for missing outcome data in randomized control trials, especially when imputing intervention and control groups separately to avoid excluding interactions from the imputation model.[136] I used the *mice* package,[133] which allowed me to specify the predictor matrix to account for the clustered nature of the data and specify that clusters may impact the outcome by updating the default method for binary variables (since the outcome variable was the only binary variable in the imputation

matrix) to a generalized linear mixed model (I replaced *logreg* with *2l.bin*).[137] In accordance with best practices in multiple imputation, the imputation model also included the other baseline psychometric and clinical data available in HoPS+ (**Table 2**) and I used 25 imputations – which was equal or greater than the covariate or outcome with the greatest proportion of missing data (approximately 23%, rounded up to the nearest 5).[88,137] Imputation objects for the control and intervention group, which had the same settings and random seeds, were merged to allow for a pooled analysis that utilized Rubin's rules to calculate accurate standard errors and effect estimates.[136,137] Of note, the *MMLB* package creates an output object that does not work with multiply imputed datasets, so I wrote updated functions based on the *mice* package's *pool* function, using Rubin's rules, to pool coefficients and standard errors across imputations.[133] Furthermore, the *geesmv* package, which implements the Mancl and DeRouen variance correction, uses a GEE package that caused some problems with my final models.[130] I therefore re-wrote the Mancl and DeRouen variance correction function to work with a different GEE package, *geepack*.[129] The updated functions are available in the Chapter 4 code and the "Additional Code" folder for this dissertation on my GitHub: https://github.com/dannysack/dissertation. In one sensitivity analysis, I assumed that all participants with missing outcome data were not using modern postpartum contraceptives (likely case). In another, I assumed that all participants with missing outcome data in the control group were using modern postpartum contraceptives and all those in the intervention group were not to assess how this "worst-case scenario" impacted model estimates (**Table 7**). Finally, I assessed effect modification by female partner total (perceived plus needed) social support with an

interaction term between intervention group and total social support score. I would have liked to plot the marginal effects plot, however did not have time to figure it out for the MMM version and the GEE version was not working when I finished my analysis: https://github.com/strengejacke/ggeffects/issues/222.

Table 7. Aim 2 Analyses and Sensitivity Analyses

*Modern Postpartum Contraceptive Uptake**

1) Unadjusted analysis comparing postpartum contraceptive uptake by group clustered by clinical site
2) Adjusted analysis comparing postpartum contraceptive uptake by group controlling for the covariates from **Figure 9**, clustered by clinical site
3) Alternative adjusted analysis comparing postpartum contraceptive uptake by group controlling for the covariates from **Figure 9**, clustered by clinical site
4) Complete case adjusted analysis comparing postpartum contraceptive uptake by group controlling for the covariates from **Figure 9**, clustered by clinical site
5) Likely case adjusted analysis comparing postpartum contraceptive use by group assuming participants with missing data were not using contraceptives controlling for the covariates from **Figure 9**, clustered by clinical site
6) Worst-case scenario (2a assuming all participants with missing outcome data in the control group are using modern postpartum contraceptives and all participants with missing data in the intervention group are not)
7) Unadjusted analysis comparing postpartum contraceptive uptake by group controlling for the covariates from **Figure 9**, clustered by clinical site among participants enrolled before April 26, 2019 (pre-COVID-19)
8) Adjusted analysis comparing postpartum contraceptive uptake by group controlling for the covariates from **Figure 9**, clustered by clinical site among participants enrolled before April 26, 2019 (pre-COVID-19)
9) Adjusted analysis comparing postpartum contraceptive uptake by group controlling for the covariates from **Figure 9**, clustered by clinical site, with an interaction term between the intervention and female total social support.

*If $\sigma^2 < 0.2$, I will use an MMM for my unadjusted (1), primary (2), complete case (4), sensitivity (5, 7, 8), and worse-case scenario (6) analysis and run a GEE with MD correction for an additional sensitivity analysis (3).
*If $\sigma^2 \geq 0.2$, I will use a GEE with MD correction for my unadjusted (1), primary (2), complete case (4), sensitivity (5, 7, 8), and worse-case scenario (6) analysis and run an MMM for an additional sensitivity analysis (3).

4.2 Results

Included female HoPS+ participants were equally likely to report modern contraceptive use in the control (33.4%) and intervention (31%) groups, however, women in the intervention group were more likely to have missing information on modern postpartum contraceptive uptake (22.8% vs. 9.5%) (**Table 8**). Participants in the intervention group were more likely to use injectable contraceptives (20.2% vs. 12.4%), whereas participants in the control group were more likely to report using oral contraceptive pills (the data source did not differentiate between combined oral contraceptive pills and progesterone only contraceptive pills) (18.4% vs. 9.1%) (**Table 8**).

Table 8. Modern Contraceptive Uptake by HoPS+ Group

	Control (n = 461)	Intervention (n = 416)
Modern Contraceptive Use		
Yes	154 (33.4%)	129 (31.0%)
No	263 (57.0%)	192 (46.2%)
Missing	44 (9.5%)	95 (22.8%)
Modern Contraceptive Method		
None	263 (57.0%)	192 (46.2%)
Injectables	57 (12.4%)	84 (20.2%)
Oral Contraceptive Pills*	85 (18.4%)	38 (9.1%)
Intrauterine Device	6 (1.3%)	2 (0.5%)
Implant	4 (0.9%)	2 (0.5%)
Condom	1 (0.2%)	0 (0%)
Missing	45 (9.8%)	98 (23.6%)
Time to Measured Contraceptive Use (days)		
Median [Q1, Q3]	351 [181, 563]	357 [168, 558]
Missing	216 (46.9%)	266 (63.9%)

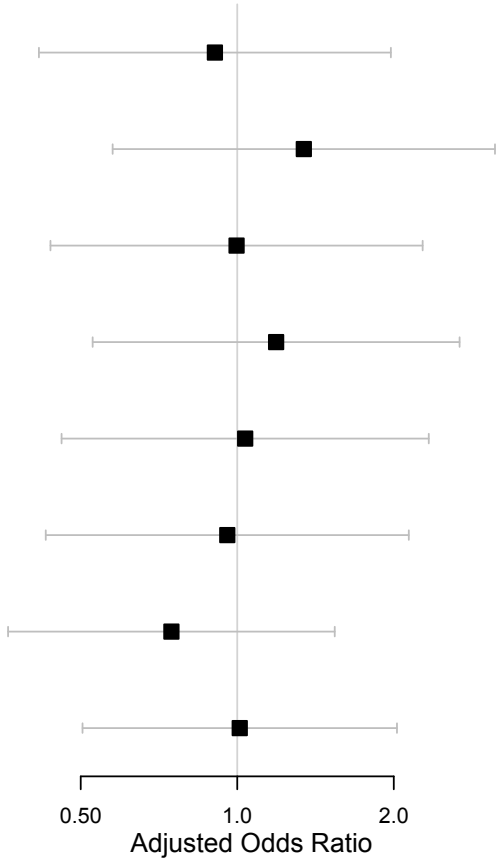
Q1: first quartile
Q3: third quartile

*Available data do not differentiate between combined and progesterone-only contraceptive pills

The unadjusted analysis revealed a σ^2 that ranged from 0.012 to 0.198 (all less than 0.20), so my primary analyses used MMM models (**Figure 14**). While none of the models reached statistical significance, the adjusted primary model (except for the GEE model not controlling for WHO clinical stage or district due to convergence issues and the worst-case scenario model) provided weak support to the hypothesis that the HoPS+ intervention may lead to increased modern postpartum contraceptive uptake (primary model (2) odds ratio [OR] 1.34, 95% confidence interval [CI] 0.58, 3.13). This direction persisted, but was even weaker, in the complete case analysis, assuming participants with missing data did not use contraceptives, and when only including participants who completed HoPS+ components 11 months before COVID-19 pandemic-induced pause. Even in the worst-case scenario, where individuals with missing data in the control group were assumed to be using contraceptives and those in the intervention group were assumed not to be using contraceptives, the effect was very close to the null (OR 0.96, 95% CI 0.43, 2.14). Finally, when assessing for effect modification between intervention group and total social support (assessed as an interaction between a binary exposure and continuous effect modifier), the interaction term p-value (0.14) did not support differential effects depending on participant social support.

Figure 14. Primary Analysis Results Across Sensitivity Analyses

Analysis	Odds Ratio (95% CI)
1) MMM Unadjusted Analysis	0.91 (0.415, 1.974)
2) MMM Adjusted Analysis	1.34 (0.576, 3.131)
3) GEE with MD Variance Correction Adjusted Analysis	1 (0.437, 2.273)
4) Outcome Complete Case MMM Adjusted Analysis	1.19 (0.527, 2.677)
5) Likely Outcome MMM Adjusted Analysis	1.04 (0.459, 2.335)
6) Worst−Case MMM Sensitivity Analysis	0.96 (0.428, 2.138)
7) MMM Unadjusted Pre−COVID−19 Analysis	0.75 (0.362, 1.54)
8) MMM Adjusted Pre−COVID−19 Analysis	1.01 (0.504, 2.028)



Adjusted analyses controlled for registration day, age, district, WHO HIV clinical stage, female and male education, and female perceived and needed social support. Analysis (3) did not include WHO HIV clinical stage or district due to model convergence challenges.
Abbreviations: MMM: Marginalized Multilevel Model; GEE: Generalized Estimating Equations; MD: Mancl and DeRouen

4.3 Discussion

While modern postpartum contraceptive uptake data from lower- and lower-middle-income countries from the early 2010s ranged around 30%, with Mozambique at 11% in 2011,[33,138] more recent estimates in Mozambique suggest that around 36% of women are using modern contraceptive methods.[139] Modern postpartum contraceptive method uptake (~30% overall, predominantly injectables and oral contraceptives) among HoPS+ participants aligns with these more recent data.[139] The high prevalence of oral contraceptive pill use among HoPS+ participants may also have clinical implications given that ~73% of female HoPS+ participants used antiretroviral regimens containing Efavirenz – a non-nucleoside reverse transcriptase inhibitor (internal HoPS+ data, 2021). Some data suggest that Efavirenz may marginally decrease the efficacy of certain formulations of combined oral contraceptives (and the combined oral contraceptives may marginally decrease the efficacy of Efavirenz), which is not the case with progesterone-only contraceptives such as injectables.[140]

Furthermore, the HoPS+ intervention effect estimates are similar to effect estimates from other studies that assessed the impact of partner engagement on postpartum contraceptive uptake, most of which did not include people with HIV (Sack et al. 2022, *Contraception*, Under Review). For example, Daniele et al. (2018) assessed interactive group discussions for male partners and couples counseling and the antenatal and postpartum period and found an increased likelihood of the use of effective modern postpartum contraceptives at 12 months (Risk Ratio 1.12, 95% CI: 1.01, 1.24).[27]

While this is reassuring, given that HoPS+ includes several, likely complementary, components, the intent-to-treat analysis in **Aim 2** only comments on whether enrollment

in the HoPS+ trial at an intervention clinic leads to increased modern postpartum contraceptive uptake, not whether the intervention itself leads to increased modern postpartum contraceptive uptake. Additionally, due to the lack of specificity in my outcome secondary to factors outside of my control (data collection and availability), these results are difficult to interpret. Following the RoB-2 risk of bias process for this analysis,[63] I would assign this analysis as having "some concerns" or even a "high" risk of bias. While the randomization process and deviations from the intended intervention domains would have "low" risk of biases, bias due to missing outcome data, outcome measurement, and selection of the reported result (due to the change imposed by the available outcome data) would all be at "some concern" for bias. Hopefully, when data collection concludes, there are less missing contraceptive outcome data.

Given the ambiguity of the outcome, measurement error likely impacts the results of this analysis. Given that my outcome is binary, non-differential outcome misclassification, if it exists, will bias the effect estimate towards the null, however, it is impossible to determine how misclassification across the levels of covariates will influence the effect estimate.[141] For example, several of the participants classified as not using modern postpartum contraceptives were recorded as not using contraceptives the same day they delivered. It is unclear whether that was the only time they were asked or counseled about postpartum contraceptives – which would be a failure of the health system – or the only data available at this point. It is also unclear how that may differ between participants in the HoPS+ intervention versus control groups. Fortunately, the "likely outcome" and "worst-case scenario" outcome assignments did not lead to major changes in my effect estimates. While quantitative bias analyses may provide useful

insights into how potential differential outcome misclassification may influence my results, that would require further assumptions about outcome misclassification and implementation across imputed datasets, which is beyond the scope of this dissertation.

Compared to other studies that assessed the impact of couples-based interventions on postpartum contraceptive uptake (Sack et al. 2022, *Contraception*, Under Review), there may be a lower risk of social desirability bias in this analysis. In any study that assesses postpartum contraceptive uptake, it is conceivable that a woman not using modern postpartum contraceptives will report that she was using one (social desirability bias). In this analysis, HoPS+ study personnel entered clinical data directly into our study collection forms (or data was available via the health record directly). This means that health care providers provided the data, which may have been more accurate given that providers know if they gave a participant an injection or prescribed oral contraceptive pills. It is still possible that participants were not using their preferred method consistency (e.g., condoms or pills), decreasing its effectiveness.

Finally, the baseline characteristics distribution by clinic and group suggest that all three primary causal inference assumptions (exchangeability, positivity, and consistency)[142] were met (after covariate adjustment) in this study. Additionally, HoPS+ participants seemed to be fairly representative of Zambézia Province,[73,78–80] which increases the likelihood that these findings are generalizable to rural regions similar to Zambézia across Mozambique. While it is unfortunate that there is no resounding evidence that randomization into the HoPS+ intervention arm improved modern postpartum contraceptive – which would be nice for me and potentially lifechanging for HoPS+ participants – no evidence suggests that randomization into the HoPS+ intervention arm

decreased modern postpartum contraceptive uptake. Future analyses and implications are discussed in more detail in the future directions chapter, Chapter 6, with context from all three aims taken together.

5. Specific Aim III: Dose-response relationship between HoPS+ components and modern postpartum uptake.

The HoPS+ intervention included three distinct, but likely complementary components: couples counseling sessions, visits from an expert peer couple for ongoing personalized support, and joint prenatal care visits. There was, however, heterogeneity in how engaged each couple was with each component of the intervention. This provided an opportunity to explore how each component of HoPS+ was related to modern postpartum contraceptive uptake. Additionally, I could assess the impact the number of completed antenatal visits in the control group on modern postpartum contraceptive uptake. Antenatal visit data were not available at the time of writing, so I focused on female and male attendance at counseling sessions and expert peer couple sessions separately.

5.1 Approach to Aim 3: Assess the dose-response relationship between HoPS+ components – counseling and peer support sessions – in the intervention group among female and male partners and modern postpartum contraceptive initiation and continuance during the 12 months after live birth.

5.1.1 Hypotheses:

Aim 3a: For each additional counseling and skills session and expert peer support couple session that a pregnant person in the intervention group attends, they will have increased odds of modern postpartum contraceptive uptake during the 12 months after live birth.

Aim 3b: For each additional counseling and skills session and expert peer support couple session that a nonpregnant partner in the intervention group attends, their

pregnant partner will have increased odds of modern postpartum contraceptive uptake during the 12 months after live birth.

5.1.2 Exposure(s) of Interest: The exposures for **Aim 3** were the number of counseling and skills sessions and peer support sessions (continuous variables) among female and male partners in the intervention group. I created a single exposure variable that combine attended counseling and skills sessions and peer support sessions into one variable. The denominator for counseling and skills sessions (six) and peer support sessions (nine) was the same for all participants. Since I included participants who may not have had a chance to complete all scheduled counseling and skills or peer support sessions, I normalized the exposures to:

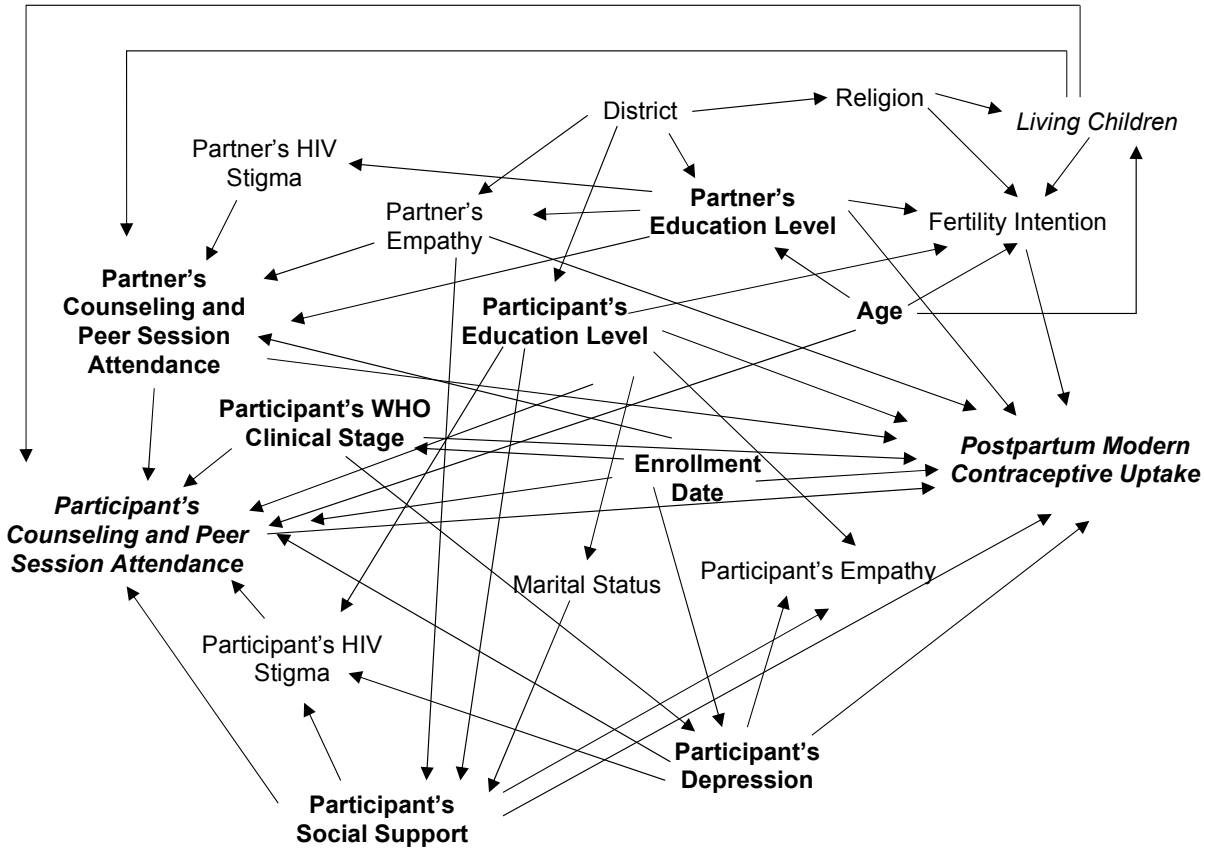
$$E_{prop} = \frac{n_c + n_p}{N_c + N_p}$$

Where n_c was the number of completed counselling or skills sessions, n_p was the number of completed peer support sessions, N_c was the number of scheduled counselling or skills sessions (maximum of 6), and N_p was the number of scheduled peer support sessions (maximum of 9).

5.1.3 Primary Outcome: The primary outcome was the same as in Aim 2, postpartum modern contraceptive uptake,[31] originally defined as modern contraceptive initiation and continuation documented in the medical record 12 months from live birth (dichotomous outcome). As in Aim 2, the outcome was updated to postpartum modern contraceptive use any time during the postpartum period, with the datapoint closest to 12 months postpartum used in cases where HoPS+ study data conflicted with medical record data.

5.1.4 Other Predictors (covariates): The covariates considered in Aim 3a and 3b are represented in **Figures 15**. Boldface indicates measured variables in the minimally sufficient set, italics indicates an unmeasured or potentially unmeasured variable in the minimally sufficient set, and bold and italics indicates the exposure and outcome. There were two minimally sufficient sets of covariates.[143] Set 1 included participant depression (continuous), female and male education (no education, some primary, completed primary, some secondary, completed secondary, college/higher education), participant WHO clinical stage (ordinal), participant social support (continuous), partner HoPS+ engagement (continuous), participant age (continuous), date of enrollment (continuous), and participant number of living children (continuous). Set 2 included participant depression (continuous), female and male education (no education, some primary, completed primary, some secondary, completed secondary, college/higher education), participant WHO clinical stage (ordinal), participant social support (continuous), partner HoPS+ engagement (continuous), partner empathy (continuous), participant age (continuous), date of enrollment (continuous), and participant fertility intention (continuous). Unfortunately, HoPS+ did not have access to fertility intentions and or access to number of living children, however, given that minimally sufficient Set 1 included fewer covariates, that is the set of variables represented in **Figure 15** for **Aim 3a** and **3b**. Partner HoPS+ engagement included counseling and peer support sessions. There was also a small chance that clinical records would reveal number of living children, which also made Set 1 the more appealing for these analyses, however, those data were, unfortunately, not available.

Figure 15. Directed Acyclic Graph for Aim 3a – Participants in the HoPS+ Intervention Group



5.1.5 Statistical Analysis:

Aim 3 fit a generalized linear mixed effects model among those in the intervention arm. All iterations of the model included the number of skills sessions and peer support sessions attended by the relevant participant (**Aim 3a**: female, **Aim 3b**: male), the composite proportion of sessions attended by their partner as a covariate, and were weighed by stabilized inverse probability weights as described below. I approximated an *a priori* effective sample size of 134 (26.6% of 504 women) in **Aim 3**. That meant, using 15 participants per degree of freedom, I could spend 9 degrees of freedom in **Aim 3**. In both models because of the small effective sample sizes, I decided to use propensity

scores to more efficiently assess the relationship between intervention fidelity among female (**Aim 3a**) and male (**Aim 3b**) partners and contraceptive uptake.

Assessing a multi-level continuous exposure required special considerations when creating a propensity score, although, fortunately, including the clustering variable as a fixed effect when creating the propensity score should have still allowed for an accurate assessment of causal effects, especially when using a random effects outcome model.[144] I therefore compared parametric covariate balanced generalized propensity scores (CBPS) with ordinal logistic regression (ORM) and ordinary least squares (OLS) fixed effect models to model the continuous exposures.[144–146] While CBPS and OLS weighting models are implemented in *WeightIt* in *R*,[147] I had to write *de novo* code for ORM weighting based on Naimi et al. (2014).[146] All code is available in the Chapter 5 code for this dissertation on my GitHub: https://github.com/dannysack/dissertation.

Propensity scores were derived from all covariates identified on the directed acyclic graph for each aim necessary to control for confounding (**Figure 15**) and based on the likelihood of (continuous) intervention fidelity, with continuous covariates modeled flexibly using restricted cubic splines with four knots. They also included a fixed effect for each participant's clinic, given that including a fixed effect in propensity scores and a random effect in the outcome model for continuous treatments has been shown to result in unbiased effect estimates.[144] I used propensity score weighting to avoid excluding any individual participants (as opposed to matching) and assessed covariate balance via absolute correlation coefficients across all participants and clustered by clinic.[148–150] I used the propensity score with the fewest mean absolute correlation coefficients greater than 0.1 across imputed datasets in my primary analysis, which indicated low

correlation between the weighted covariate distribution and the exposure.[148–150] If different methods gave similar results, I examined effective sample size after propensity score weighting as a tie-breaker. The final model was weighted by the propensity scores that best balanced baseline covariates in both **Aim 3a** in **Aim 3b** and further adjusted for partner attendance proportion at all sessions.

As in **Aim 2**, I used multiple imputation (with 25 imputed datasets) to account for missing covariate and clustered outcome data.[137] For missing data, I constructed propensity score weights for each imputed dataset and combined effect estimates using Rubin's rules, as described in Leyrat et al. (2019).[151] I then assessed covariate balance and effective sample sizes across the imputed datasets. I conducted several sensitivity analyses. I conducted a sensitivity analysis where I assume that all participants with missing outcome data were not using modern postpartum contraceptives (similar to the likely case analysis in **Aim 2**). Although I considered comparing the two best propensity score methods per the criteria described above via propensity score weighting to their models including the propensity score as a restricted cubic spline with five knots, that comparison is not appropriate in the continuous setting (whereas it would be in the binary or categorical case).[152] I therefore considered propensity score weighting with all available baseline covariates (except for occupation and relationship status due to singularity issues), given the uncertainty inherent to the directed acyclic graphs (**Figure 15**). In addition to the above-described sensitivity analyses, given the evidence for residual confounding from the directed acyclic graph (**Figure 15**), I calculated the E-value to assess how much confounding from this missing covariate would "explain away" any statistically significant association between HoPS+ intervention components

and modern postpartum contraceptive since number of living children is not reliably available from the medical record.[153,154] Instead of calculating the E-value for the effect estimate, I did so for the lower bound of the confidence intervals of statistically significant positive effects.

5.2 Results

Overall, female HoPS+ participants in the intervention group were more likely attend their scheduled counseling and skills sessions (median 100% of scheduled sessions vs. 50% among male participants) and peer sessions (89% vs. 56%) than male participants (**Table 9**). Participants in the intervention group who attended fewer than six counseling and skills or nine peer sessions were either informally lost to follow up, missed one or more visits, or were enrolled sufficiently recently that they were not eligible to enroll in all visits at the time the data were pulled. This last set of participants is better reflected in the rows that show the proportion of sessions completed (**Table 9** and **Figure 16**). **Figure 16** shows female participants were more likely to attend all HoPS+ intervention components than male participants.

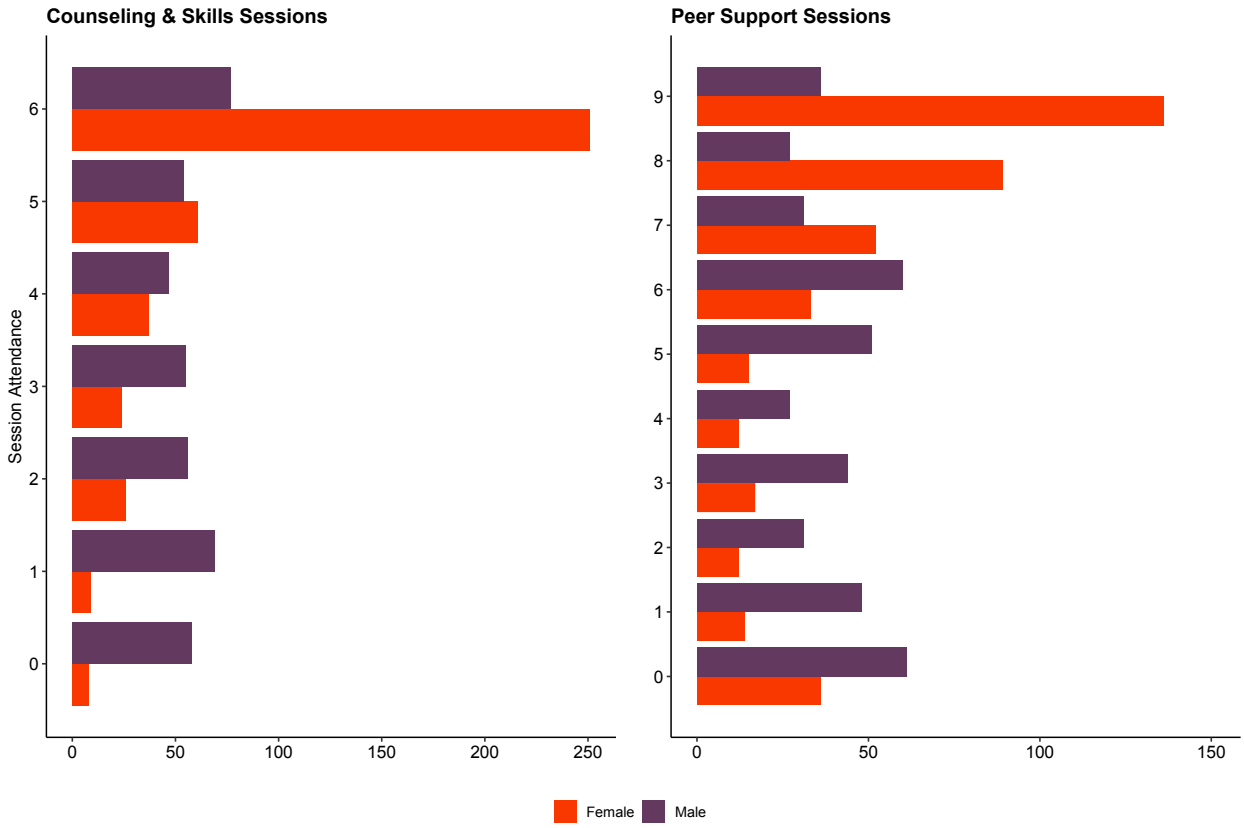
Table 9. HoPS+ Intervention Engagement by Sex

	Female Participants (n = 416)	Male Participants (n = 416)
Completed Counseling & Skills Sessions		
0	8 (1.9%)	58 (13.9%)
1	9 (2.2%)	69 (16.6%)
2	26 (6.3%)	56 (13.5%)
3	24 (5.8%)	55 (13.2%)
4	37 (8.9%)	47 (11.3%)
5	61 (14.7%)	54 (13.0%)
6	251 (60.3%)	77 (18.5%)
Proportion of Scheduled Attended		
Median [Q1, Q3]	1.00 [0.833, 1.00]	0.500 [0.167, 0.833]
Completed Peer Sessions		
0	36 (8.7%)	61 (14.7%)
1	14 (3.4%)	48 (11.5%)
2	12 (2.9%)	31 (7.5%)
3	17 (4.1%)	44 (10.6%)

Table 9. HoPS+ Intervention Engagement by Sex

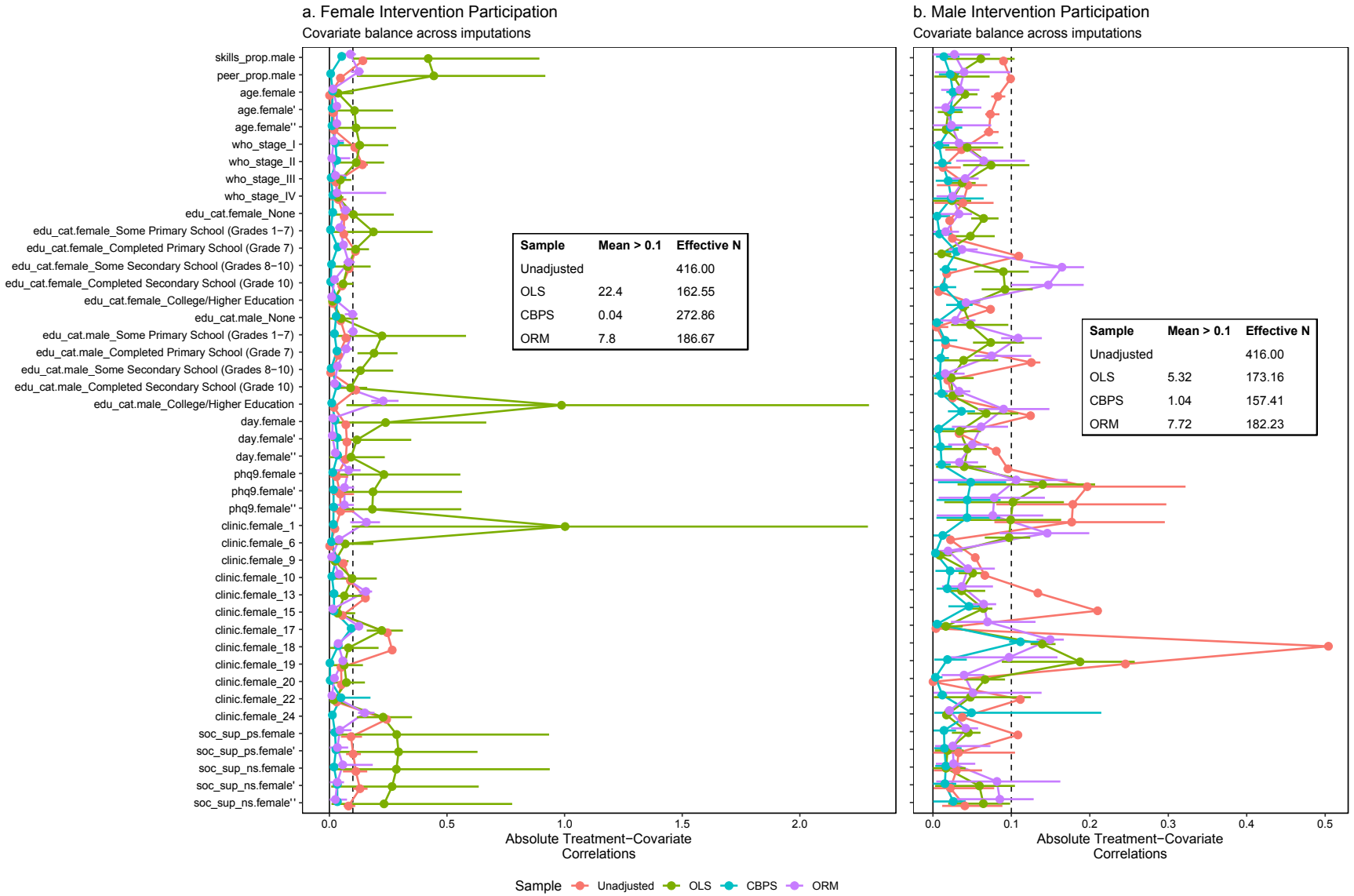
	Female Participants (n = 416)	Male Participants (n = 416)
4	12 (2.9%)	27 (6.5%)
5	15 (3.6%)	51 (12.3%)
6	33 (7.9%)	60 (14.4%)
7	52 (12.5%)	31 (7.5%)
8	89 (21.4%)	27 (6.5%)
9	136 (32.7%)	36 (8.7%)
Proportion of Scheduled Attended		
Median [Q1, Q3]	0.889 [0.667, 1.00]	0.556 [0.222, 0.667]
Total Attendance of Scheduled Sessions (Proportion)		
Median [Q1, Q3]	0.929 [0.800, 1.00]	0.533 [0.333, 0.733]

Figure 16. HoPS+ Intervention Component Attendance by Sex



As described above, in my primary analysis for Aim 3, I assessed covariate balance using three different propensity score weighting methods with the covariates from **Figure 15**. These results are presented in **Figure 17**, with results for female participants presented in panel (**a**) and results for male participants presented in panel (**b**). **Figure 17a** shows that the CBPS (blue) weighting method is superior across all included covariates in reducing the absolute treatment-covariate correlations for female and male participants with balanced covariates across all imputations (mean number of covariate correlations > 0.1 of 0.04 and 1.04 for females and males, respectively). **Figure 17** also shows that the ORM (purple) weighting method is the next best method across all included covariates for females and the third best for males. It is unclear why some of the correlations are greater than 1 with OLS weighting in both cases (more noticeable in females). Of the 416 included participants in the HoPS+ intervention group, the CBPS propensity score weighting populations were the closest in size to the original study population among females (272.86 for CBPS compared to 186.67 for OLS and 162.55 for ORM), whereas the ORM method had the highest effective sample size in males. For the primary analyses, I therefore used CBPS weighting for female and male participants.

Figure 17. Covariate Balance Across Female and Male HoPS+ Participants – Primary Analyses

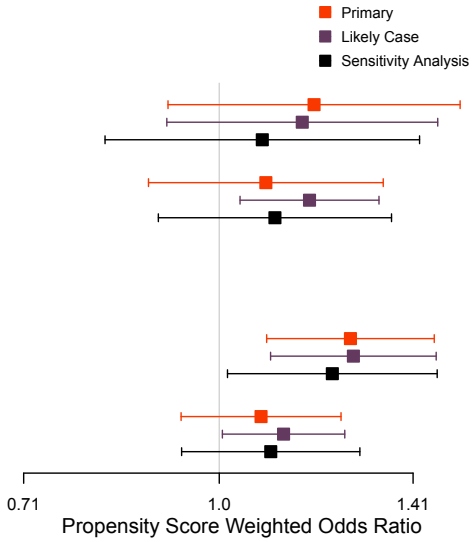


Mean > 0.1 is the mean number of unbalanced covariates (with a correlation > 0.1) across the 25 imputed datasets.

I then used the CBPS stabilized inverse probability weights to assess the impact of each additional counseling and skills session and each additional peer session in female and male participants for the primary and likely case outcomes described in **Aim 2** (**Figure 18**). Data from a sensitivity analysis, described below, are also presented in **Figure 18** for completeness. While additional session attendance was not statistically significantly associated with postpartum modern contraceptive uptake among female participants, expect for peer session attendance in the likely case scenario (OR 1.17, 95% CI: 1.04, 1.33), each additional counseling and skills for male participants was associated with increased modern postpartum contraceptive uptake in their female partner (OR: 1.26, 95% CI: 1.09, 1.46).

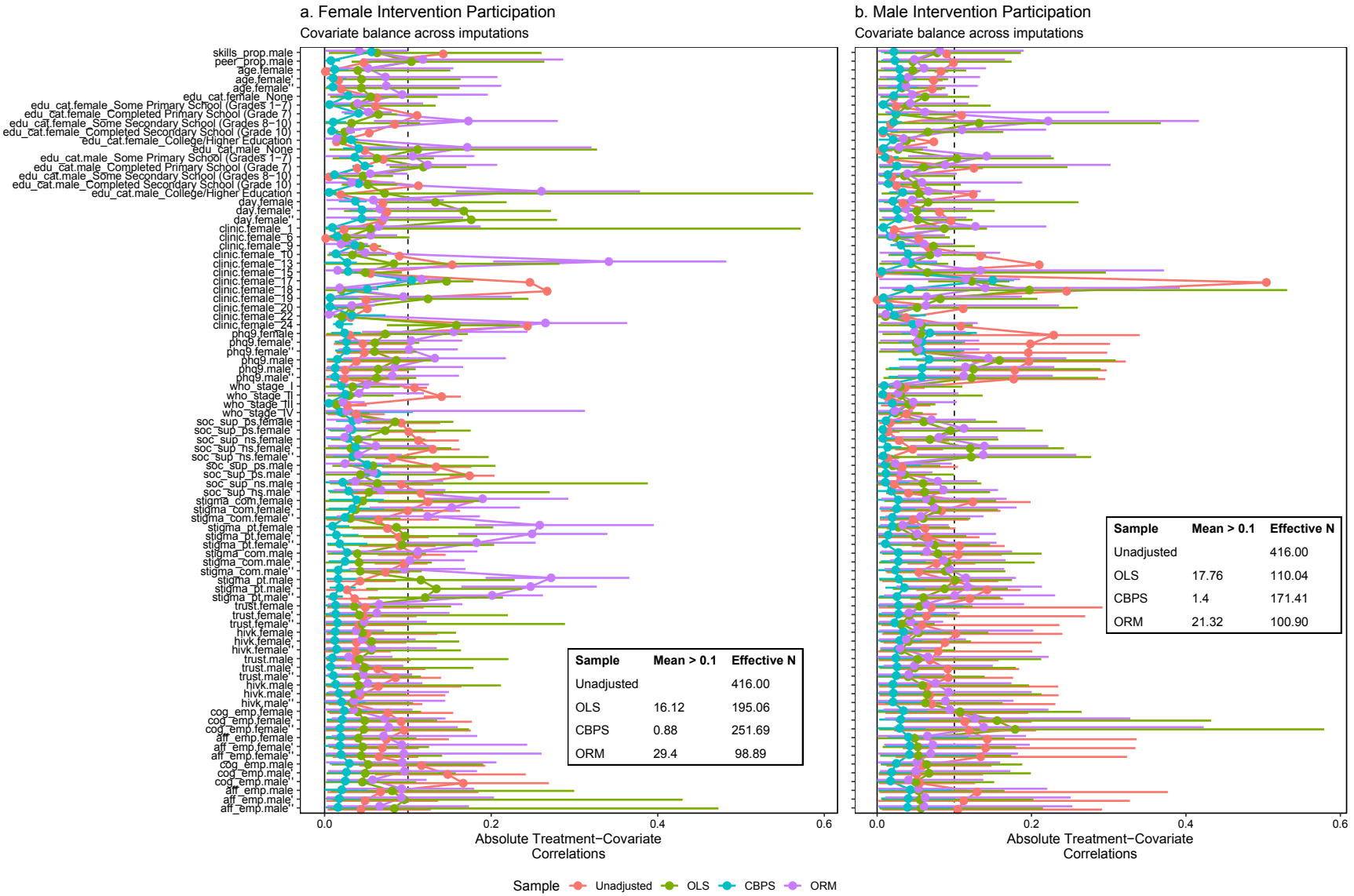
Figure 18. Propensity Score Weighted Effect Estimates of Additional HoPS+ Intervention Component on Modern Postpartum Contraceptive Uptake

	Odds Ratio (95% CI)		
Female Participant*	**Primary Analysis**	**Likely Case**	**Sensitivity Analysis**
+1 Counseling & Skills Session	1.18 (0.913, 1.533)	1.16 (0.911, 1.473)	1.08 (0.817, 1.426)
+1 Peer Session	1.09 (0.882, 1.337)	1.17 (1.038, 1.327)	1.1 (0.898, 1.357)
Male Participant*			
+1 Counseling & Skills Session	1.26 (1.088, 1.464)	1.27 (1.095, 1.469)	1.22 (1.015, 1.472)
+1 Peer Session	1.08 (0.935, 1.241)	1.12 (1.006, 1.249)	1.1 (0.935, 1.283)



*CBPS weighting

Figure 19. Covariate Balance Across Female and Male HoPS+ Participants – Sensitivity Analysis



Mean > 0.1 is the mean number of unbalanced covariates (with a correlation > 0.1) across the 25 imputed datasets.

I then assessed how including additional covariates when generating the propensity scores impacted covariate balance and the model effect estimates (**Figure 18 & 19**). In an updated assessment of propensity score weighting methods with more included covariates, CBPS weighting worked best across both female and male participants in terms of effective sample size (251.69 and 171.41) and had the fewest mean number of covariates with absolute treatment-covariate correlations greater than 0.1 (0.88 and 1.4) in females and males (**Figure 19**). The updated effect estimates, presented in **Figure 18 & Table 10**, result in mildly blunted effect estimates for female and male attendance. An additional session of counseling and skills session for male participants, for example, is now associated with a smaller increased likelihood of modern postpartum contraceptive uptake in their female partner (OR: 1.22, 95% CI: 1.02, 1.47) than with the directed acyclic graph inverse probability weights.

Table 10. Odds Ratios and 95% Confidence Intervals for Primary Weighting and Sensitivity Weighting Scenario

	Primary Analysis (n = 416)	Likely Case (n = 416)	Sensitivity Analysis (n = 416)
	OR (95% CI)	OR (95% CI)	OR (95% CI)
Female			
+1 Counseling & Skills Session	1.18 (0.913, 1.533)	1.16 (0.911, 1.473)	1.08 (0.817, 1.426)
+1 Peer Session	1.09 (0.882, 1.337)	1.17 (1.038, 1.327)	1.1 (0.898, 1.357)
Weighting Method	CBPS	CBPS	CBPS
Mean Correlations > 0.1	0.04	0.04	0.88
Effective N	272.86	272.86	251.69
Male			
+1 Counseling & Skills Session	1.26 (1.088, 1.464)	1.27 (1.095, 1.469)	1.22 (1.015, 1.472)
+1 Peer Session	1.08 (0.935, 1.241)	1.12 (1.006, 1.249)	1.1 (0.935, 1.283)
Weighting Method	CBPS	CBPS	CBPS
Mean Correlations > 0.1	1.04	1.04	1.4
Effective N	157.41	157.41	171.41

Abbreviations: CBPS: covariate balancing propensity scores; ORM: proportional odds model; OR: odds ratio; CI: confidence internal; Total N: Total Sample Size; Mean Correlations > 0.1: mean correlations > 0.1 with weighting method across 25 imputations; Effective N: sample size after weighting across 25 imputations

Finally, I calculated to assess how any unmeasured confounding may impact the relationship between each statistically significant exposure and the outcome for the relevant confidence interval bound. In this case, the E-value that would lead the confidence interval to include the null (no effect) for male partners attending an additional counseling and skills session was 1.4.

5.3 Discussion

This analysis, which found that increased male partner attendance at counseling and skills sessions was associated with increased female partner postpartum modern contraceptive uptake in the postpartum period, has several important implications. It provides additional evidence that non-pregnant partner engagement during the antenatal period contributes to postpartum contraceptive uptake, or that session attendance among non-pregnant partners shows they were supportive prior to the intervention. Future trials or interventions may benefit from studying outcomes in couples with supportive partners at the trial onset and improving intervention adherence among non-pregnant partners.

Additionally, although the CBPS worked best in this case, this analysis provides a practical example of Naimi et al. (2014)'s use of proportional odds models to generate continuous propensity score weights and extends it from purely continuous exposures (which were grouped into quintiles in Naimi et al.'s paper) to count exposures (which are not a binned continuous variable).[146]

While there is some evidence that couples-based interventions increase postpartum contraceptive uptake, existing studies do not explicitly examine how male partner intervention adherence may impact postpartum contraceptive uptake or even describe

male partner intervention adherence (Sack et al. 2022, *Contraception*, Under Review). Daniele and colleagues (2018), for example, found variable male partner adherence across several components of their intervention.[27] While 77% of male partners attended an interactive group, only 64% attended antenatal couples counseling session and 56% attended the postpartum couples counseling session.[27] Males enrolled in the HoPS+ trial attended approximately 50% counseling and skills sessions and 56% of peer sessions (which were more likely to be at the participants' homes). Of note, these estimates are still preliminary – due to COVID-19-incuded study delays – and the COVID-19 pandemic likely impacted intervention adherence. Interestingly, counseling and skills sessions seemed to be more efficacious than peer sessions. This could reflect the additional training among counseling and skills session facilitators compared to peer support couples – some HoPS+ participants noted that peer counselors only discussed medication adherence in the qualitative interviews. It could also reflect the higher barrier to attend counseling and skills sessions. For example, perhaps participants who did attend were already more engaged in care and session attendance was just a proxy for engagement. Assuming the former, these results suggest that couples-based interventions may benefit from focusing attention on increasing non-pregnant partner engagement.

Naimi et al. (2014) used a proportional odds model to create propensity score weights for a continuous exposure via quintile binning.[146] Proportional odds models have been used more broadly when modeling ordinal or continuous outcomes, however, without the need for outcome binning.[88,155] Furthermore, evidence suggests not binning outcomes improves statistical power when using proportional odds models.[88] I therefore

extended Naimi et al.'s approach and did not bin the HoPS+ exposure, but instead left it as an ordinal exposure. It preformed similarly to well-established methods (OLS and CBPS) for reducing exposure-covariate associations when generating propensity score weights. The primary potential limitation was that it resulted in marginally (and in the sensitivity analysis dramatically) lower effective sample sizes than the other two methods. This was not the case when fewer covariates were included in the propensity score model when I was testing the code, which may be relevant for other settings with fewer measured potential confounders. I am actively working with Dr. Bryan Shepherd and Dr. Laurie Samuels to write up this variation on calculating inverse probability weights for ordinal exposures.

There are several additional limitations inherent to this analysis. Condensing all components of the intervention into one exposure to generate the propensity score assumed that each confounding variable was related to each intervention component in the same way. Additionally, combining all counseling and skills sessions and peer sessions into two count exposures in the final model assumed that each single session (for each intervention component) contributed equally to modern postpartum contraceptive uptake. This is likely not true, and it is likely that heterogeneity exists between how different components of the HoPS+ intervention impact different participants and their partners. Unfortunately, given the small sample size (particularly the low outcome prevalence) I could not test the impact of each session individually. Finally, while I assumed I could treat effect estimates as the average treatment effects after propensity score weighting, the literature on continuous propensity scores, to my

knowledge, has not directly addressed estimand assessment for continuous exposures.[144–146,148,149]

6. Conclusions and Future Directions

6.1 Summary of Conclusions

This dissertation added the following novel components to the scientific literature:

- Augmented existing frameworks on contraceptive decision-making and pregnancy spacing among people living with HIV in sub-Saharan Africa (**Aim 1**, **Chapter 3**)
- Assessed the impact of being in the HoPS+ intervention group on modern contraceptive uptake (**Aim 2**, **Chapter 4**)
- Provided insight into how adherence to different HoPS+ intervention components – counseling and skills sessions and peer support sessions – among female and male HoPS+ participants impacted modern postpartum contraceptive uptake (**Aim 3**, **Chapter 5**)

This project further elucidated the nuanced relationship between HIV, gender dynamics, and contraception, which has, to this point, been insufficiently studied. Researchers, clinicians, and policy makers may be able to take insights from these data to support the ongoing efforts to decrease unintended pregnancies and maternal and child mortality. Below, after considering the impact of COVID-19 on this project, I present conclusions, potential future directions, and analytic suggestions for future studies assessing similar phenomena or using similar data sources.

6.2 Implications of the COVID-19 Pandemic

I would be remiss not to mention the other global pandemic that, in many ways, influenced this dissertation, COVID-19. While my primary analysis was an intention-to-treat analysis, and I included a time covariate in my analyses, the pandemic may have differentially impacted adherence in the treatment and control HoPS+ trial arms. If there

was lower adherence in the treatment arm, given that it required greater participant engagement to be adherent in the treatment arm, my results likely underestimate the effect of HoPS+ on modern postpartum contraceptive uptake. This limitation is likely relevant to proposed HoPS+ analyses of the primary and secondary trial outcomes. Hernán and Hernándex-Díaz (2012) present a nice overview of alternative methods (inverse probability weighting, g-estimation, and instrumental variable estimation) to reduce bias in "as treated" and "per protocol" analyses and their respective assumptions and limitations.[164] Given that HoPS+ included longitudinal collection of key confounders, it may be uniquely situated to implement "as treated" and "per protocol" analyses, which may provide a more comprehensive assessment of its intervention's effect on retention in care, viral suppression, and maternal-to-child transmission.

6.3 Aim 1

When the HoPS+ qualitative interviews were paused due to the COVID-19 pandemic (**Figure 3**), I identified alternative questions related to the incorporation of male partners into antenatal care or contraceptive uptake based on the qualitative questions directed at HoPS+ participants and providers (**Appendix 3**). These questions could be addressed with the methods described in **Chapter 3** (**Aim 1**):

1) From HoPS+ providers: Perceived (pre-implementation) and actual (18 months post-implementation) challenges and benefits to providing partner-based services to expectant and postpartum couples? Suggestions for improved implementation strategies?
2) From HoPS+ participants and health care providers: the value of utilizing peer counselors to provide psychosocial and educational support to couples to

navigate the cultural and clinical difficulties encountered when the couple is HIV positive (outside of HIV counseling)?

These questions address important aspects of the HoPS+ intervention that could either directly influence postpartum contraceptive uptake (such as barriers to contraceptive availability) or suggest strategies to improve postpartum contraceptive uptake (such as more targeted or additional counseling and skills sessions). They are also highly relevant to the HoPS+ trial's primary outcome – 12-month retention in HIV care – and secondary outcomes – viral suppression in female and male partners at 18 months and maternal-to-child HIV transmission at 18 months.

After having completed the analysis, these questions remain relevant. In particular, given the higher HoPS+ session adherence among interviewed participants than all participants in the intervention arm, asking providers about implementation challenges may be instructive given that they interacted with individuals who attended many and few sessions.

6.4 Aim 2

While I was primarily interested in how to estimate an effect estimate for a binary outcome using marginal models for application to the HoPS+ trial's secondary outcomes, my module with Dr. Jonathan Schildcrout also provided valuable insight into the analysis for the primary outcome, a continuous measure of retention in HIV care. While generalized linear mixed effect models (GLMM) and GEE generate equivalent effect estimates with continuous outcomes, GLMM provides a "cluster-specific" or conditional effect rather than a the "population-average" or marginal effect from GEE.[156] This is relevant because in a cluster-randomized trial, such as HoPS+, participants in

the same cluster all receive the same intervention. While GEE is known to underestimate variance when there are fewer than around 40 clusters, several methods for variance correction exist in the *geesmv* package in *R*,[130] most of which are also relevant for continuous outcomes, including the MD correction I used in **Aim 2**.[123,157] The *geesmv* package implements the *gee* function from the *gee* package in *R* when calculating variance corrections.[130] I found that the *gee* function struggled when models included multiple categorical covariates. I therefore re-wrote the *GEE.var.md* function from *geesmv* package to use *geeglm* from *geepack*,[129,130] which may be relevant for primary HoPS+ analyses. The HoPS+ team could also consider additional strategies to correct GEE variance with small numbers of clusters such as double robust inverse probability weighted augmented GEE, which has the added benefit of being developed specifically for cluster-randomized trials with missing outcomes.[158,159] Implemented in the *CRTgeeDR* package in *R*, this type of GEE gives accurate effect estimates whether either the missing data process or the outcome model is correctly specified.[158,159] Prague et al (2016) provides *R* code for how to implement doubly robust GEE in their *CRTgeeDR* package as a supplemental file.[158,159]

Additionally, future analyses could assess time-to-event outcomes, such as time to contraceptive start date in the postpartum period (when more complete start date data are available) using a Cox proportional hazards model with robust standard errors (clustered by clinic).[160,161] These models would be similar to the primary analysis in **Aim 2**, but would include a right censored outcome and modeling the log-hazard of postpartum contraceptive uptake.[160,161] If the proportional hazards assumption does not

hold after assessing covariates via a global chunk test of Schoenfeld residuals, the analysis could employ a marginal Weibull model clustered by clinic location.[161]

6.5 Aim 3

This analysis also has implications for secondary analyses of primary outcomes in the HoPS+ trial that assess intervention adherence and can provide a framework for detailed adherence-based analyses. The scope of this work somewhat limited the analytical options. Each session, at least of the counseling and skills HoPS+ component, also focused on different skills that may be differently relevant to different outcomes (**Appendix 3**). Future analyses could consider how attendance at particular sessions impact various outcomes. For example, session six focuses on “Reducing Sexual Risks and Dealing with HIV”. A future analysis could assess how attendance at this session, or partner attendance, influences outcomes such as HIV stigma or HIV knowledge.

Additionally, if I had additional time, I would consider the temporal relationship between each HoPS+ session. It is reasonable to assume that attending one session increases the likelihood that a participant attends the next session. It is also likely that other factors around each session influence the likelihood of attending the next session. This sort of analysis would need to consider time-varying exposures and confounding with inverse probability weighting or g-computation methods.

Finally, **and most importantly**, the movement to incorporate partners in antenatal care has, somewhat unsurprisingly but still disappointingly, proceeded largely without eliciting pregnant people’s perspectives. It is entirely possible, and in fact likely, that some partners should not be engaged in care. These include, but are not limited to,

partners who pressure pregnant people not to take their antiretroviral therapy, partners who threaten to disclose pregnant people's HIV status, partners who coerce pregnancy, and partners who perpetrate interpersonal violence.[162,163] I am working with Dr. Audet, and collaborators in South Africa, to develop a scale to assess partner characteristics that will eventually allow practitioners to tailor services offered to pregnant people and their partners to address this oversight.

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8. Appendices

8.1 Appendix 1: Demographic and Clinical Data Collection

Supplemental Table 1: HoPS+ Demographic and Clinical Data on Each Participant

Variable	Variable Type	Source	Notes
1. District	Categorical	Baseline Survey, Medical Record	
2. Health facility	Categorical	Baseline Survey, Medical Record	
3. Urban (yes/no)	Categorical	Medical Record	The definitions for this are pre-determined by type of health facility (HF) and geographic location of HF, so this information comes just from identifying which HF they are seeking care (similar to #4)
4. Main (*sede*) health facility (yes/no)	Categorical	Baseline Survey, Medical Record	
5. Unique Patient ID	Free Text	Medical Record	
6. Sex	Categorical	Baseline Survey, Medical Record	
7. Date of birth	Date	Baseline Survey, Medical Record	
8. Age (years), at enrollment	Continuous	Baseline Survey, Medical Record	Each participant reports their age and REDCap calculates it from their date of birth and date of enrollment
9. Employment status at the time of enrollment (adults only)	Categorical	Baseline Survey, Medical Record	Initially collected as free text, before being changed to a drop-down menu including: Farmer, Domestic Worker, Businessman, Fisherman, or Other
10. Highest level of education	Categorical	Baseline Survey, Medical Record	Initially collected as free text (continuous), before being changed to a drop-down menu including: none, grades 1-7, finished grade 7, grades 8-10, finished grade 10, grade 11, grade 12, university, other
11. Marital status of the patient (adults only)	Categorical	Baseline Survey, Medical Record	Initially collected as free text, before being changed to a drop-down menu including: Married, Single, or Living Together
12. Sexual preference/orientation	Categorical	Medical Record	This variable is captured in the medical record, but we expect lots of missingness
13. Village, town, or city of residence at ART initiation	Free Text	Baseline Survey	

14.	Previous ART enrollment (yes/no)	Dichotomous	Medical Record	
15.	Previous ARV regimen before patient was LTFU (if applicable)	Categorical	Medical Record	
16.	ART regimen at re-initiation/initiation (current medication regimen)	Categorical	Medical Record	
17.	Enrollment date (current)	Date	Medical Record Baseline Survey	Enrollment in HIV services
18.	ART initiation date (current)	Date	Medical Record	
19.	WHO clinical stage at ART initiation, and date of documentation	Continuous/Date	Medical Record	
20.	CD4+ cell count (cells/mm^3) 'at enrollment' and date of sample collection	Continuous/Date	Medical Record	Taken between enrollment and 1 month after enrollment
21.	All CD4+ cell counts (cells/mm3) and dates of sample collections	Continuous/Date	Medical Record	Repeated Measurements
22.	Viral load, first result obtained at or after enrollment, and results of any other VL tests, and date of sample collection	Continuous/Date	Medical Record	Per MoH guidelines: pregnant women with HIV should receive their first viral load (VL) test after 3 months on ART (not at enrollment into ART services). Additionally, non-pregnant adults (i.e. male partners in this case) should receive their first VL test after 6 months on ART.
23.	All previous TB investigation results (positive/negative), and date of investigation	Dichotomous/Date	Medical Record	
24.	Previous date of enrollment in TB services (if applicable)	Date	Medical Record	
25.	Previous TB treatment completed (if applicable)	Dichotomous	Medical Record	
26.	Previous date TB treatment completed (if applicable)	Date	Medical Record	
27.	Current enrollment in TB services, at (ART) enrollment, and date of documentation	Dichotomous/Date	Medical Record	
28.	Weight (kg), at enrollment, and at all other clinic visits, and date of documentation	Continuous/Date	Medical Record	Repeated Measurements
29.	Height (m^2), at enrollment, and date of documentation	Continuous/Date	Medical Record	
30.	Body mass index (kg/m^2) at enrollment, and at all other clinic visits, and date of documentation	Continuous/Date	Medical Record	Repeated Measurements, calculated based on weight and height
31.	Hemoglobin, at enrollment, and at all other clinic visits, and date of documentation	Continuous/Date	Medical Record	Repeated Measurements

32.	Blood pressure, at enrollment, and at all other clinic visits, and date of documentation	Continuous/Date	Medical Record	Repeated Measurements
33.	Alanine Transferase (ALT) at enrollment, at ART initiation, and date of documentation	Continuous/Date	Medical Record	Based on our teams' experience, this variable is often missing
34.	Creatinine at enrollment, at ART initiation, and date of documentation	Continuous/Date	Medical Record	Based on our teams' experience, this variable is often missing
35.	Patient status (active, default, LTFU, transfer, or death) at 6, 12 and 18 months after enrollment	Categorical	Medical Record	This is a variable captured and tracked in the medical record
36.	Dates of all ART pick-ups, including next scheduled	Date	Medical Record	Repeated Measurements
37.	Dates of all clinic visits, including next scheduled	Date	Medical Record	Repeated Measurements
38.	Date cotrimoxazole prescribed	Date	Medical Record	Trimethoprim/Sulfamethoxazole
39.	Patient reported use of IV drugs	Dichotomous	Medical Record	
40.	Patient reported use of tobacco	Dichotomous	Medical Record	
41.	Patient reported use of alcohol	Dichotomous	Medical Record	
42.	Estimated due date of pregnant female patient	Date	Medical Record	
43.	Initiation of any family planning method and date of initiation	Categorical/Date	Medical Record	Collected within study records via manual collection from medical record
44.	Continuation of any family planning method and date of continuation	Categorical/Date	Medical Record	Repeated Measurements; also collected within study records via manual collection from medical record
45.	Final patient outcome status and date of final status	Categorical/Date	Medical Record (primary); Study records (secondary)	Options include: a) Transfer out of care at that facility, and date of transfer out; b) death, date of death recorded, cause of death where available; c) LTFU, date of most recent visit (LTFU defined as not returning for >60 days past last scheduled appointment / pick-up date)
46.	Number of babies with this pregnancy	Continuous	Study Records and Medical Record	
47.	Date of birth of infant	Date	Study Records and Medical Record	
48.	Infant status at birth	Dichotomous	Study Records and Medical Record	Stillbirth or Livebirth

49.	Infant sex	Categorical	Study Records and Medical Record	
50.	Weight of infant at birth, and at all other clinic visits, and date of documentation	Continuous/Date	Medical Record	Repeated Measurements
51.	Whether infant received ART prophylaxis after birth, date of start, and type of ARV	Dichotomous/Categorical/Date	Medical Record	
52.	Data on infant feeding practices where available		Medical Record	Would require manual data collection from medical logbooks, includes data on breastfeeding, and any nutritional support required
53.	Date of any PCR testing for infant, and test results	Dichotomous/Date	Study Records and Medical Record	Repeated Measurements
54.	Date of any HIV rapid testing for infant, and test results	Dichotomous/Date	Study Records and Medical Record	Repeated Measurements
55.	Data on discharge from services (transfers, referrals, abandoned, died), and date	Categorical/Date	Medical Record and Study Records	
56.	Health status of child at 18 months	Dichotomous	Study Records and Medical Record	Alive or Dead
57.	HIV health status of child at 18 months (HIV-positive, HIV-negative)	Dichotomous	Study Records and Medical Record	HIV-positive or HIV-negative

HoPS+: Homens para Saúde Mais trial
The medical record is OpenMRS (Open Medical Record System)

Supplemental Table 2: HoPS+ Antenatal Care Specific Indicators (Aggregated)

Variable
1. Number of pregnant women who arrived for first ANC appointment
2. Number of pregnant women who know their serostatus, known positive
3. Number of pregnant women who know their serostatus, recently tested
4. Number of pregnant women who received HIV test results in ANC, first test (positive, negative, and indeterminate results)
5. Number of pregnant women who received HIV test results in ANC, repeat test, positive, negative, and indeterminate results)
6. Number of HIV+ pregnant women enrolled in ANC
7. Number of HIV+ pregnant women who received ARVs to reduce risk of MTCT (NVP, AZT+NVP, initiated ART, and already on ART)
8. Number of pregnant women receiving CTZ upon entrance to ANC
9. Number of HIV+ pregnant women that initiate prophylaxis with CTZ
10. Number of HIV+ pregnant women who are clinically malnourished (moderate or severe acute malnutrition)
11. Number of HIV+ pregnant women who receive nutritional support (supplemental and therapeutic)
12. Number of HIV-negative pregnant women who receive nutritional support (supplemental and therapeutic)
13. Number of pregnant women in ANC with previous HIV-negative results
14. Number of partners of pregnant women present in ANC
15. Number of partners of pregnant women who tested for HIV in ANC
16. Number of partners of pregnant women who tested for HIV in ANC and received results (positive, negative, or indeterminate)
17. Number of HIV+ partners of pregnant women who initiated ART in ANC.

HoPS+: Homens para Saúde Mais trial; ANC: Antenatal Care; MTCT: maternal to child transmission; NVP: Nevirapine; AZT: Zidovudine; ART: antiretroviral therapy; CTZ: Cotrimoxazole
All of these aggregated data come from medical records/programmatic data in the District Health Information Software database

8.2 Appendix 2: Psychometric Scales

8.2.1 Interpersonal Reactivity Index

The Interpersonal Reactivity Index (IRI) consists of four empathy domains with seven questions each (28 questions total).[71] The fantasy scale assesses one's ability to place oneself in fictional situations; the perspective-taking scale reflects one's ability to understand another person's point of view; the empathic concern scale measures one's ability to have caring feelings towards another individual; and the personal distress scale characterizes an individual's own negative feelings when witnessing adverse events in others.[71] The fantasy and perspective taking scales constitute the cognitive component of empathy, while the empathic concern and personal distress scales constitute the affective component of empathy.[71] More recent research further supports that distinct cognitive and affective empathy domains undergird the IRI scale.[165–169] This includes the development of two-factor empathy scales[167,168] and imaging and molecular research that suggest distinct, but interrelated, cognitive and affective neural circuitry.[166,169]

Each item is scored on a 5-point Likert-like scale ranging from "Does not describe me well" (0) to "Describes me very well" (4). Although the original IRI contains nine reverse scored items, in the process of the above-described scale adaptation all questions were positively phrased and scored to avoid confusion during translation and survey administration and improve response accuracy among participants with fewer years of education. Previous validations report Cronbach's alpha values for IRI subscales from 0.70-0.83 and correlation coefficients of 0.01-0.37 between subscales.[71,170–172] HoPS+ participants are markedly different from the college-educated study participants and junior high school students participating in previous IRI validations.[170–172] Although the

IRI has been used in South Africa as a composite 28-item scale or in its 4-subscale form,[173,174] to my knowledge it had never been validated in or adapted to sub-Saharan Africa. I worked with Dr. Audet and other HoPS+ collaborators to validate a 13-item version (using items from the original scale) that includes a cognitive subscale (7 items, Cronbach's alpha 0.78) and an affective subscale (6 items, Cronbach's alpha 0.73) among HoPS+ participants.[72]

8.2.2 Van Rie et al. Stigma Scale

The Van Rie et al. Stigma scale was developed in participants in Thailand and includes 11 questions that assess perceived community stigma (community stigma scale) and 10 questions that assess patient felt/experienced stigma (personal stigma scale).[76] Each item is scored on a Likert-type scale from "strongly disagree" (0) to "strongly agree" (3). A re-validation in the United States divided the personal stigma scale into two subscales, the Loss of Social Relationships subscale (three questions) and the Managing HIV Concealment subscale (four questions), and shortened the Perceived Community Stigma subscale (eight questions).[175] Cronbach's alpha for subscales were between 0.69-0.91 and correlation coefficients were between 0.51-0.59 on previous validations.[76,175]

I collaborated with other members of the HoPS+ team to revalidate this scale using baseline data from 967 couples (1,937 individuals) enrolled in the HoPS+ trial (Frisby et al., 2021, AIDS and Behavior, Under Review). The updated version, which was validated in individuals participants and within couples, includes a patient felt/experienced stigma dimension (5 items, Cronbach's alpha 0.79) and a perceived community stigma dimension (12 items, Cronbach's alpha 0.93) (Frisby et al., 2021, AIDS and Behavior, Under Review).

8.2.3 Hall et al. Medical Profession Trust Scale

The Hall et al. Medical Profession Trust scale was developed among 502 American adults recruited through random digit dialing.[176] Participants were mostly female (68%) and 58% had at least some college education.[176] The final scale includes 11 items and one factor (Cronbach's alpha 0.89) that assesses general trust with questions that address fidelity (items 1-2), competence (3 & 7), honesty (5 & 10), and global trust (4, 6, 8, 9, and 11) on 5 point Likert-type scales from completely disagree (1) to completely agree (5).[176] Their final scale was associated with interpersonal physician trust, satisfaction with care, and propensity to follow doctors' recommendations.[176]

I collaborated with other members of the HoPS+ team to revalidate this scale using baseline data from 967 couples (1,937 individuals) enrolled in the HoPS+ trial, which resulted in a single 8-item scale (Cronbach's alpha 0.71) validated in individuals and within couples (Frisby et al., 2021, AIDS and Behavior, Under Review).

8.2.4 Berlin Social Support Scales

The Berlin Social Support scale was developed in Germany to assess cognitive and behavioral aspects of social support.[75] Each item is scored on a 4-point response scale including "strongly disagree," "disagree," "agree," and "strongly agree" from 1-4. We included the 4-question perceived emotional support subscale (original Cronbach's alpha of 0.73), 4-question perceived instrumental support subscale (original Cronbach's alpha of 0.69), 4-question need for social support subscale (original Cronbach's alpha of 0.63), and 5-question seeking social support subscale (original Cronbach's alpha of 0.81).[75] Variants of the Berlin Social Support Scale have been used in a variety of settings in Europe and North America.[177–180]

I collaborated with other members of the HoPS+ team to revalidate this scale in participants and within couples using baseline data from 967 couples (1,937 individuals) (Frisby et al., 2021, AIDS and Behavior, Under Review). The updated version includes two, instead of four, factors: a perceived support dimension (7 items, Cronbach's alpha 0.78) and a need for support dimension (8 items, Cronbach's alpha 0.75) (Frisby et al., 2021, AIDS and Behavior, Under Review).

8.2.5 HIV Knowledge-27

The HIV Knowledge-27 (HK-27) measures participant HIV knowledge with 27 questions that were developed and validated in collaboration with partners in Zambézia Province.[70] Participants either answer "agree", "disagree", or "uncertain" – which is included to discourage guessing – and get one point for a correct answer and zero points for an incorrect or "uncertain" answer.

8.2.6 Patient Health Questionaire-9

The Patient Health Questionaire-9 (PHQ-9) measures the nine attributes that characterize major depressive disorder.[181] Participants rate each attribute from 'Not at all' (0) to 'Nearly every day' (3) and were considered depressed if they scored 10 or greater. The PHQ-9 has been validated to screen PLWH in SSA and Mozambique for depressive symptoms[74,182–184] and has been used to measure depressive symptoms in Mozambique.[73]

Supplemental Table 3. Original and Adapted Interpersonal Reactivity Index (IRI)

Question (subscale)	Original Questions (Davis 1980)	Adapted Questions*
1 (FS)	I daydream and fantasize, with some regularity, about things that might happen to me.	I imagine and dream, with some regularity, about things that might happen to me.
2 (EC)	I often have tender, concerned feelings for people less fortunate than me.	I often have feelings of affection and concern for people less happy than me.
3- (PT)	I sometimes find it difficult to see things from the "other guy's" point of view.	I can see things from "another person's" point of view.
4- (EC)	Sometimes I don't feel sorry for other people when they are having problems.	I do feel sorry for other people when I have problems.
5 (FS)	I really get involved with the feelings of the characters in a novel.	**I really get involved with the feelings of the characters in a movie.**
6 (PD)	In emergency situations, I feel apprehensive and ill-at-ease.	**In emergency situations, I feel afraid and ill-disposed.**
7- (FS)	I am usually objective when I watch a movie or play, and I don't often get completely caught up in it.	I'm not normally objective when I watch a movie or game, and I often get completely caught up in it.
8 (PT)	I try to look at everybody's side of a disagreement before I make a decision.	I try to look at everybody's side of a disagreement before I make a decision.
9 (EC)	When I see someone being taken advantage of, I feel kind of protective toward them.	When I see someone taken advantage of, I feel a little protective against them.
10 (PD)	I sometimes feel helpless when I am in the middle of a very emotional situation.	**Sometimes I feel helpless when I am in the midst of a very emotional situation.**
11 (PT)	I sometimes try to understand my friends better by imagining how things look from their perspective.	Sometimes, to try to understand my friends better, I imagine how things seem from their perspective.
12- (FS)	Becoming extremely involved in a good book or movie is somewhat rare for me.	It's a common for me to become heavily involved in a good book or movie.
13- (PD)	When I see someone get hurt, I tend to remain calm.	**When I see someone get hurt, I usually don't stay calm.**
14- (EC)	Other people's misfortunes do not usually disturb me a great deal.	**The misfortunes of other people usually disturb me much.**
15- (PT)	If I'm sure I'm right about something, I don't waste much time listening to other people's arguments.	Even if I'm sure I'm right about something, I spend time listening to other people's arguments.
16 (FS)	After seeing a play or movie, I have felt as though I were one of the characters.	**After seeing a play or movie, I feel like I'm one of the characters.**
17 (PD)	Being in a tense emotional situation scares me.	**Being in an emotional and tense situation scares me.**
18- (EC)	When I see someone being treated unfairly, I sometimes don't feel very much pity for them.	**When I see someone being treated unfairly, I feel much pity for them.**
19- (PD)	I am usually pretty effective in dealing with emergencies.	I tend to be ineffective in dealing with emergencies.
20 (EC)	I am often quite touched by things that I see happen.	I am often very touched by things that I see happen.
21 (PT)	I believe that there are two sides to every question and try to look at them both.	**I believe there are two sides to every question and I usually look at both.**
22 (EC)	I would describe myself as a pretty soft-hearted person.	I would describe myself as a very kind person.
23 (FS)	When I watch a good movie, I can very easily put myself in the place of a leading	**When I watch a good movie, I can easily put myself in the place of the main character.**

	character.	
24 (PD)	I tend to lose control during emergencies.	I tend to lose control during emergencies.
25 (PT)	When I'm upset at someone, I usually try to "put myself in his shoes" for a while.	**When I'm upset with someone, I tend to try to put myself in their place for a while.**
26 (FS)	When I am reading an interesting story or novel, I imagine how I would feel if the events in the story were happening to me.	**When a film is interesting, I wonder how I would feel if the events in the story were happening to me.**
27 (PD)	When I see someone who badly needs help in an emergency, I go to pieces.	When I see someone who needs help in an emergency, I become torn apart.
28 (PT)	Before criticizing somebody, I try to imagine how I would feel if I were in their place.	**Before criticizing somebody, I try to imagine how I would feel if I were in their place.**

Cognitive Empathy Subscales: Fantasy Scale (FS) and Perspective Taking (PT)
Affective Empathy Subscales: Personal Distress (PD) and Empathic Concern (EC)
Boldface indicates inclusion on the validated version[72]
"-" indicates that the question was originally negatively coded
* Homens para Saúde Mais (HoPS+) trial questions after translation to Portuguese and adaptation to the cultural norms in Zambézia Province, Mozambique
Final Cognitive Scale Questions: 5, 16, 21, 23, 25, 26, 28
Final Affective Scale Questions: 6, 10, 13, 14, 17, 18

Supplemental Table 4. Original and Adapted Van Rie et al. HIV Stigma Scale

Question	Original Question (Van Rie et al. 2008)	HoPS+ Question*
1	Some people think that those with HIV are disgusting	**Some people think that people HIV are unpleasant**
2	Some people do not want those with HIV playing with their children	**Some people do not want people with HIV to play with their children**
3	Some people feel uncomfortable being near those with HIV	**Some people feel uncomfortable when they are around people with HIV**
4	Some people do not want to talk with others with HIV	**Some people do not want to talk to people with HIV**
5	Some people keep distance from people with HIV	**Some people keep their distance from people with HIV**
6	If a person has HIV, some community members will behave different towards that person for the rest of her or her life.	**If a person has HIV, some community members treat that person differently for the rest of their life**
7	Some people try not to touch others with HIV	**Some people try not to touch people with HIV**
8	Some people are afraid of those with HIV	**Some people are afraid of people with HIV**
9	Some people think that people with HIV are unclean	**Some people think that people with HIV are live in a bad way**
10	Some people prefer not to have those with HIV living in their community	**Some people prefer not to have people with HIV living in their community**
11	Some people think that people with HIV get what they deserve	**Some people think that people with HIV get what they deserve**
12	Some people who have HIV feel hurt because of how others react to knowing they have HIV	**Some people with HIV feel hurt by how others react to knowing they have HIV**
13	Some people who have HIV feel alone	Some people with HIV feel alone
14	Some people who have HIV are afraid that other people in the community will talk about them having HIV	**Some people with HIV are afraid that other people in the community will talk about them having HIV**
15	Some people who have HIV lose friends when they share with them they have HIV	Some people with HIV lose friends when they share with them that they have HIV
16	Some people who have HIV are afraid to tell those outside their family that they have HIV	**Some people with HIV are afraid to tell people outside their family that they have HIV**
17	Some people who have HIV worry that others will reveal their secret	**Some people with HIV worry that other people will reveal their secret**
18	Some people who have HIV try very hard to keep the issue of having HIV a secret	*NOT TRANSLATED*
19	Some people who have HIV keep their distance from others to avoid spreading the HIV virus	**Some people with HIV keep their distance from others to avoid spreading the HIV virus**
20	Some people who have HIV feel guilty because their family has the burden of caring for them	Some people with HIV feel guilty because their family has to take care of them
21	Some people who have HIV will choose carefully who they tell about having HIV	**Some people with HIV will carefully choose who they tell them they have HIV**

* Homens para Saúde Mais (HoPS+) trial questions after translation to Portuguese and adaptation to the cultural norms in Zambézia Province, Mozambique
Boldface indicates inclusion on the validated version (Frisby et al., 2021, AIDS and Behavior, Under Review)
Community Perspectives Questions: 1-11, 19
Patient Perspectives Questions: 12, 14, 16, 17, 21

Supplemental Table 5. Original and Adapted Wake Forest Medical Profession Trust Scale

Question	Original Question (Hall et al. 2002)	HoPS+ Question*
1	Doctors in [general] care about their patients' health just as much or more as their patients do	**Your doctor cares about your health as much or more than you do**
2	Sometimes doctors care more about what is convenient for them than about their patients' medical needs ***(q6 on original)***	*If your doctor asked you to participate in a medical study, you would be concerned that he or she would focus more on the study than on what is best for you* ***(q7 on original)***
3	Doctors are extremely thorough and careful ***(q12 on original)***	***Your doctor will listen with care and concern to any problems you may have, even with small or foolish problems (not on original)***
4	You completely trust doctors' decisions about which medical treatments are best	**You completely trust your doctor's decisions about which medical treatments are best for you**
5	Doctors are totally honest in telling their patients about all of the different treatment options available for their conditions	**Your doctor is completely honest, informing you of all the different treatment options available for your condition.**
6	Doctors think only about what is best for their patients	**Your doctor only thinks of what is best for you**
7	Sometimes doctors do not pay full attention to what patients are trying to tell them ***(q18 on original)***	*Your doctor sometimes pretends to know things when he or she is not really sure* ***(q16 on original)***
8	Doctors always use their very best skill and effort on behalf of their patients	**Your doctor always uses his best skill and effort for you**
9	You have no worries about putting your life in the hands of doctors	**You have no worries about putting your life in the hands of your doctor**
10	A doctor would never mislead you about anything ***(q22 on original)***	*Do you worry that your doctor can share sensitive information about you with people who don't have to know it* ***(q19 on original)***
11	All in all, you trust doctors completely	**All in all, you have complete confidence in your doctor**

* Homens para Saúde Mais (HoPS+) trial questions after translation to Portuguese and adaptation to the cultural norms in Zambézia Province, Mozambique
Italics indicates questions that were incorrectly left in after trimming the questionnaire
Boldface indicates inclusion on the validated version (Frisby et al., 2021, AIDS and Behavior, Under Review)
Physician Trust Questions: 1, 3-6, 8-9, 11

Supplemental Table 6. Original and Adapted Berlin Social Support Scale

Question	Original Question	HoPS+ Question*
1 (PES)	There are some people who truly like me.	**Some people really like me.**
2 (PES)	Whenever I am not feeling well, other people show me that they are fond of me.	**Whenever I do not feel well, other people show me that they like me.**
3 (PES)	Whenever I am sad, there are people who cheer me up.	**Whenever I am sad, there are people who cheer me up.**
4 (PES)	There is always someone there for me when I need comforting.	**There is always someone available to me when I need comforting.**
5 (PIS)	I know some people upon whom I can always rely.	I know some people who I can always trust.
6 (PIS)	When I am worried, there is someone who helps me.	**When I'm worried, there is someone who helps me.**
7 (PIS)	There are people who offer me help when I need it.	**There are people who offer me help when I need.**
8 (PIS)	When everything becomes too much for me to handle, others are there to help me.	**When everything becomes too much for me, there are others available to help me.**
9 (NfS)	When I am down, I need someone who boosts my spirits.	**When I'm down, I need someone to cheer me up.**
10 (NfS)	It is important for me always to have someone who listens to me.	**It is important for me to always have someone who listens to me.**
11 (NfS)	Before making any important decisions, I absolutely need a second opinion.	**Before making any important decisions, I absolutely need a second opinion.**
12- (NfS)	I get along best without any outside help.	I feel best without any outside help.
13 (SS)	In critical situations, I prefer to ask others for their advice.	**In critical situations, I prefer to ask for advice from others.**
14 (SS)	Whenever I am down, I look for someone to cheer me up again.	**Whenever I am sad, I look for someone to cheer me up again.**
15 (SS)	When I am worried, I reach out to someone to talk to.	**When I am worried, I look for someone I can talk with.**
16 (SS)	If I do not know how to handle a situation, I ask others what they would do.	**If I don't know how to handle a situation, I ask others what they would do.**
17 (SS)	Whenever I need help, I ask for it.	**Whenever I need help, I ask for it.**

PES: Perceived Emotional Support; PIS: Perceived Instrumental Support; NfS: Need for Support; SS: Support Seeking

"-" indicates that the question was originally negatively coded

* Homens para Saúde Mais (HoPS+) trial questions after translation to Portuguese and adaptation to the cultural norms in Zambézia Province, Mozambique

Boldface indicates inclusion on the validated version (Frisby et al., 2021, AIDS and Behavior, Under Review)

Perceived Support Questions: 1-4, 6-8

Seeking Needed Support Questions: 9-11, 13-17

Supplemental Table 7. HIV Knowledge 27 Scale*

Question	Original Questions (Ciampa 2012)
1	HIV and AIDS are the same thing.
2	A person with HIV can look and feel healthy.
3	A cure for AIDS exists.
4	A blood test can tell if a person has been infected with HIV.
5	A person who feels sick from AIDS can feel better by taking medicines.
6	A woman who has HIV can give it to her infant during birth.
7	A woman who has HIV can give it to her infant while breastfeeding.
8	A pregnant woman who has HIV can prevent her baby from becoming infected by taking medicine.
9	A person can get HIV by getting an injection with a needle that was already used on someone else.
10	A person can get HIV by sharing blades.
11	A person can get HIV from mosquito bites.
12	A woman can get HIV if she has sex with a man who has HIV.
13	A person can get HIV by sharing forks, spoons or cups with a person who has HIV.
14	A person with HIV can cure the infection by taking medicine.
15	Eating healthy foods can keep a person from getting HIV.
16	Coughing and sneezing spread HIV.
17	A person can get HIV by shaking hands with someone who has HIV.
18	A person can get HIV by a curse.
19	A person who has HIV can use medicine to prevent becoming sick with AIDS.
20	A person can seek protection from a traditional healer to avoid getting AIDS.
21	A man can get HIV if he has vaginal sex with a woman who has HIV.
22	Bathing or washing one's genitals after sex keeps a person from getting HIV.
23	A person cannot get HIV by having oral sex, mouth-to-penis, with a man who has HIV.
24	Having sex with more than one partner can increase a person's chance of being infected with HIV.
25	A man wearing a latex condom during sex can lower his chance of getting HIV.
26	A person with another STD, such as syphilis, is more likely to get HIV.
27	Cleaning of the vagina with soap before or after sex will keep a woman from getting HIV.

* The HIV Knowledge 27 Scale was developed in this population, in Portuguese and Echuabo, and therefore did not change in translation for use in the Homens para Saúde Mais (HoPS+) trial

Supplemental Table 8. Original and Adapted Patient Health Questionnaire

Question	Original Question	HoPS+ Question
Prompt	How often have you been bothered by the following over the past 2 weeks?	During the last 14 days, when were you affected by any of the following problems?
1	Little interest or pleasure in doing things?	I had little interest or pleasure in doing things
2	Feeling down, depressed, or hopeless?	I felt discouraged, afraid or hopeless
3	Trouble falling or staying asleep, or sleeping too much?	I had difficulty falling asleep or sleeping without interruption, or I slept too much
4	Feeling tired or having little energy?	I felt tired or lack of energy
5	Poor appetite or overeating?	I had a lack of or excessive appetite
6	Feeling bad about yourself — or that you are a failure or have let yourself or your family down?	I felt that I didn't like myself - or that I'm a loser or that I was disappointed in myself or my family
7	Trouble concentrating on things, such as reading the newspaper or watching television?	I had a hard time concentrating on things, like reading the newspaper or watching television
8	Moving or speaking so slowly that other people could have noticed? Or so fidgety or restless that you have been moving a lot more than usual?	I moved or spoke so slowly that other people may have noticed. Or the opposite: I was agitated to the point of walking around, much more than usual
9	Thoughts that you would be better off dead, or thoughts of hurting yourself in some way?	I thought it would be better to be dead, or to hurt myself in some way

* Homens para Saúde Mais (HoPS+) trial questions after translation to Portuguese and adaptation to the cultural norms in Zambézia Province, Mozambique

8.3 Appendix 3: Adapted *CoupleConnect* Sessions and Learning Objectives

Supplemental Table 9. Couple Counseling Session Learning Objectives

Session Title	Hours	Learning Objectives: *By the end of the session, participants will be able to:*
Session 1: Communication	2.5	• Describe communication and its three phases • Correctly discern some nonverbal communication in a simulated activity • Identify any emotions they tend to exaggerate or repress • List behaviors and environments that can hinder listening and communication • Demonstrate active listening skills
Session 2: Trust and Accountability	2.5	• Identify at least one expectation that the other sex holds for couple relationships • Communicate at least two appreciations to their partner • Describe their personal experiences with trust • Describe how trust develops over time in couple relationships • Assess the current level of trust in their relationship • Verbalize a commitment to their partner to take an action to build or maintain trust in the relationship
Session 3: Preventing, Negotiating, and Resolving Conflict	2.5	• Identify some areas of difference in their couple relationship • Describe four major styles that couples use to resolve conflict • Identify their personal conflict style(s) • Identify their partner's conflict style(s) • Recognize that hostile conflict styles are damaging to relationships • Describe at least five fair fighting guidelines • Make a complaint in a soft style
Session 4: Managing Household Finances	2.5	• Identify at least two financial values that they share with their partners • Identify at least one financial goal that they share with their partners • List the steps involved in making a financial plan • Describe how to create a budget • Create a time-bounded (daily, weekly, monthly, etc.) budget with their partners
Session 5: Dealing with Life Challenges	2.5	• Identify their top five life challenges • Differentiate between constructive and destructive coping strategies • Describe some strategies for preventing an unexpected pregnancy • Identify their preferred style of receiving support from their partner • Identify their partner's preferred style of receiving support
Session 6: Reducing Sexual Risks and Dealing with HIV	2.5	• Identify how sexually transmitted infections, including HIV, are transmitted and how they can be prevented • Identify the impact of HIV in their communities and families • State how acquiring HIV has affected their lives • Discuss ways in which the couple can support each other and communicate regarding their diagnoses and treatment

8.3.1 HoPS+ Qualitative Questions

For couples in the HoPS+ intervention arm:

1. We came to visit you and your new baby! How is he/she doing? Can we see him/her?
2. How is your HIV treatment going? Have you brought your baby for HIV testing? Are you giving him/her medications? Are you having any problems with your own medication (ask husband and wife separately) or your baby's?
3. How have your sessions with your peer couple been going? (How often have you met? What advice or support have they offered? How well do you get along?)
4. How have your sessions with the counselor been going? (How often have you met? What advice or support have they offered? How well do you get along?)
5. We always want to improve our services. Do you have any suggestions to improve the work of the peer couples? (how did you like the process of linking with them? Topics of discussion? The personality of the other couple?)
6. Do you have any suggestions to improve the work of the counselor? (Topics of discussion? Assistance they provided? Where they good at their job?)
7. Aside from the things we have already covered, do you have any other suggestions for us to improve this program? (Clinical service delivery? Community-based support?)
8. How do you travel to the health facility? Do you have to pay anything to get to the health facility where you normally get HIV care and services (e.g. for the taxi, bus)? If so, how much do you and/or your family spend to get to and/or return home from the health facility?

9. Do you ever need to have someone help care for your child/children when you go to the health facility? If so, do you ever have to pay any money or give anything to that caretaker in return? If so, how much do you and/or your family pay or what do you give in return for the childcare help?
10. What kind of work do you do? Are you ever unable to go to work (either to job or to work on farm, etc.) because you have to come to the health facility instead? How many days a month? Do you lose any income from these missed days of work?
11. Are there any other costs that you and/or your family have to pay or losses of money/income related to getting HIV care or services at the health facility?

For health care workers at clinics in the HoPS+ intervention arm:

1. Can you tell us what you know about the new strategy to delivery couple-based ANC services in some of our clinical sites?
2. Have you worked with couples enrolled in the study? What are your experiences recruiting couples into the HoPS+ study? (probe: what are some reason couples refuse to participate? Why do they agree to participate?)
3. What is your opinion about delivering care to the pregnant woman and her male partner together? Do you have any suggestions for how to improve? (probe: is there enough privacy? Do you think women might hold back concerns because her partner is always there?)
    a. How did working with this couple change your vision for their future?
    b. Specifically, how has this changed your relationship with your partner?

    c. How has this changed the way you plan your future: including issues related to future children (how many more do you want)?

4. Have you received any feedback from participating couples regarding counseling sessions with HoPS+ couples counselor? Do you have any suggestions for how to improve the work of the couples counselor? (Topics of discussion? Assistance they provided? Collaboration with staff?)
    a. How has working with this Couples Counselor changed your vision for your future?
    b. Specifically, how has your relationship with your partner changed?
    c. How the way you plan your future has changed: including questions related to future children (ONLY ASK ABOUT THE DESIRED NUMBER OF CHILDREN, IF YOU HAVE NO ANSWER IN QUESTION 3); how many more do you want?
5. Have you received any feedback from participating couples regarding support sessions with HoPS+ expert peer couples? Do you have any suggestions for how to improve the work of the peer couples? (Topics of discussion? Selection process for peer couples?)
6. As a health care provider/counselor for these couples, what additional training would you like to improve your ability to do your job?
7. Aside from the things we have already covered, do you have any other suggestions for us to improve this program? (Clinical service delivery? Community-based support?)

Updated question directly relevant to postpartum contraceptive uptake after the interview pause for COVID-19:

8. Thinking of all the counseling services you've received, let's talk about your thoughts about future children.
    a. How many children do most couples typically have here in your district (or zone)?
    b. What are the most frequent reasons for having this number of children?
    c. How many children would you like to have?
    d. Was your last pregnancy planned (between you and your partner)?
    e. Have you and your partner talked about using contraception/type of family planning?
        i. Tell me about any discussions you and your partner have had about using contraception/family planning?
        ii. How did the counseling sessions in this study help you and your partner to discuss contraception/family planning use?
    f. Would you like to have more children?
        i. If so, when would you like to have the next one?
        ii. If not, are you doing anything to prevent pregnancy in your relationship?

For health care workers at clinics in the HoPS+ control arm arm:

1. Can you give us a brief description of the new HoPS+ strategy? Can you explain briefly in your own words how patient flow goes with this new strategy?

2. While this strategy is not being used here, we are curious of your opinions about the HoPS+ strategy for providing care to HIV+ couples expecting and/or with a new baby?
3. What would be your opinions about using such a strategy here?
    a. Specifically, how would you move around the clinic space to ensure couples could receive care together? Would this be difficult?
    b. What kind of additional training do you think counselors would need to provide couples counseling?
    c. What kind of additional training do you think the nurses and technicians would need to provide couples care?
    d. Are there any additional services (counseling, home-based care) that you think would be helpful for couples?
4. Do you imagine that couples in your community would be interested in this strategy? Why or why not?
5. What could we do to address any hesitation to participate among couples?
6. Aside from the things we have already covered, do you have any other suggestions for us to improve this program? (Clinical service delivery? Community-based support?)

8.4 Appendix 4: Aim 1 Codebook

Codebook (for Appendix 4)

Theme	Code (type)	Definition	Examples
Contraceptive Knowledge	Accurate Information (deductive)	Expressed factually correct information about contraceptive methods (or where to get it) and pregnancy	"It helped because he helped, right, he explained to me, I went and advised my husband, and he accepted that actually the children are little. If you don't you won't be in good health, you should rest and let the children grow up, then let's have another child later." (20-year-old female, Inhassunge) "They told us we can use a condom when we have sex outside, yes." (39-year-old male, Gilé)
	Misinformation (deductive)	Expressed factually incorrect information about contraceptive methods (or not knowing where to get it) and pregnancy	"No, she's only a year and three months, she's still very little for her mother to get pregnant again. And she is still breastfeeding, it will only be when she weans from breastfeeding….We haven't weaned her so this helps the mother avoid pregnancy, and also, right, right we didn't start having sexual intercourse because the baby is still breastfeeding" (27-year-old male, Mocubela) "I usually see women doing planning while the children are still in their belly, if they don't comply with health's law they will die." (38-year-old male, Pebane)
	New Information (deductive)	Any reference to new information that either member of the couples learned from any of the HoPS+ sessions about contraception, birth spacing, or reproduction	"It's because where we come from we didn't know there were pills you could take to decrease the number of children. So now that there is medication, if you want to have 2 or 3 then you just go to the hospital. When you go to the hospital they give you medication so those children can grow up. That's what I think now." (36-year-old male, Quelimane) "Helped me by saying that you need to give good medication for the child, medication for you too, so that you're well. If you don't give medication to the child, and if you don't take it the child will also not have good health. I memorized that...They said that in order to having children you need… if you see that you already gave birth and the child is already 2 years old and I don't give it a break, you ought to go to the hospital to ask for medication and wait for the child to grow up a little. After you see the child is at a good age, you can have another, you can stop [family] planning to have another." (20-year-old female, Inhassuge)

	Individual Fertility Desires (deductive)	Rationale for why an individual wants children (take care of them when they are old, child mortality, financial difficulties with many children, etc.) or why they want to delay or stop having children	"I would like to rest first." (20-year-old female, Mocubela) "I want to have a maximum of four (4) because if you give birth to many is not a bad thing to get old, right?" (28-year-old male, Maganja Da Costa) "May be twenty I would like (smiles), because it's good to have children at home." (20-year-old female, Gilé) "The reason I want ten children, for example, my mother only had me, only me alone, yes, the brothers all died, the mother died, and just left with dad. So is the reason I ask and say at least ten." (39-year-old male, Gilé) "They [the children] can take care of each other, welcome each other." (19-year-old female, Pebane)
Partner Motivation	Health Considerations (inductive)	Expressing that improved health has changed how an individual or partners think about having additional children or that health limits future fertility goals	"If I feel like I have good health, maybe I will think about having more children." (23-year-old male, Mocubela) "My health was very weak before taking the medication. It was health hour by hour. Now I see that it is different from what it was before. Now I go a month without feeling sick." (20-year-old female, Inhassunge)
	Economic Considerations (deductive)	Any reference to economic considerations in making fertility decisions	"It could be four… but even having four in the times we're living in, I don't know, if it was old times where you had a lot of food for children to eat, people would have 7 even 10…Now, the way I see it, these days if someone has 4 or 3 it is already too much." (27-year-old female, Inhassunge) "I used to think I could have a maximum of 3 or 4. Because here in Mozambique, to have 9 or 10 children, ehhh, poverty will add to poverty, hmm." (28-year-old male, Gilé)
	Religiosity (deductive)	How an individual considers religious preferences in fertility decisions	"Those [children] who God wants to give us, according to his will." (19-year-old female, Gilé) "Since our religion says that planning is a sin, that's why I say that it will depend on the number God wants to give me. Even if it's 1 we will thank this God who gave us 2, 3… hm." (27-year-old male, Mocubela)

	Social Norms (deductive)	Expressed social norms surrounding fertility in couples' community	"There are people who gave birth to 10 and people they say gave birth too much. Some give birth to 5 and they also say it was too much. There are people who birthed 4, 2 girls and 2 boys and they say that one birthed well...Girl pounds flour, fetches water. Boy will also take you to the hospital when you're sick, talks to the nurses, that's what a boy does. So you don't say it's not good to have a boy." (20-year-old female, Mocubela) "It depends on each person's wishes. They agree between the couple, the husband along with his wife will say, "I want these many children", the women will give birth until they reach the number they agreed on. Afterwards you just need to do family planning." (27-year-old male, Mocubela)
	Paternalism (deductive)	If the female partner reports that the male partner wants control family planning or the male partner reports wanting to control family planning	"Yes, she has been saying that "when the day comes for me to go do (family) planning, I will go to do (family) planning". So I told her that she can't do planning alone without discussing with me. We should agree first and then do the planning. That's all." (19-year-old male, Quelimane)
Barriers to Contraceptive Uptake	Gender Norms (deductive)	Examples of partners acting in ways that would be expected of them given their gender	"I don't know [how many children I would like] since my husband isn't here." (23-year-old female, Maganja Da Costa)
	Surreptitious Contraceptive Use (deductive)	References to hiding contraceptive use from partner (e.g., reporting using injectables so partner does not know)	"We didn't agree [on using family planning]. She did it and when I found out about the idea, I liked it. She said she wanted to rest. "I don't want to have another child while this one is little," I said alright." (22-year-old male, Mocubela) "When I talk he won't listen. So I want to try to "steal" by myself." (30-year-old female, Inhassunge)
Facilitators of Contraceptive Uptake	HoPS+ Engagement (deductive)	References to partner's engagement to HoPS+ intervention components, includes attendance at counseling/skills sessions or peer sessions as well as references to what a partner shared at or after any sessions	"It helped because he [the couples counselor] helped, right, he explained to me, I went and advised my husband, and he accepted that actually the children are little. If you don't you won't be in good health, you should rest and let the children grow up, then let's have another child later." (20-year-old female, Inhassunge) "Yes, my relationship with my wife really did change. I can tell you how it changed, it changed a lot because we didn't understand each other before, we would each accuse the other. So then this phase arrived, we are established, no one accuses the other, everything is normal, it's normal. We live without any problems, no arguments, we are able to talk and get over problems." (34-year-old male, Maganja Da Costa)

	Trust in Providers (deductive)	Expressed trust in providers, counselors, or peer support couples to give advice/information on contraceptive decisions	"When they arrived and gave me advice, and explained everything to me, I was free to feel that emotion, with that happiness. Yes, I like those people that were coming to the house, yes, I can't speak ill of them." (39-year-old male, Gilé)
	Partner Respect (deductive)	Expressed respect or examples of listening to or following partner's desires (or, conversely, not doing so)	"We help each other. Sometimes when I'm sick, or even my son, or I went to another place, I say, "husband go get mine for me," and if it was him, he also says, "wife go get it for me too and bring it home." We haven't argued at our home yet…It helped us because when we get home we respect each other as husband and wife, we don't fight because of this disease." (20-year-old female, Gilé)
	Shared Decision Making (inductive)	References to talking to partner (or avoiding talking to partner) about using contraception	"It depends on each person's wishes. They agree between the couple, the husband along with his wife will say, "I want these many children", the women will give birth until they reach the number they agreed on. Afterwards you just need to do family planning." (27-year-old male, Mocubela) "We have said that, "oh my friend, we have to let this child grow a little. We do the planning and when it grows up, we leave the planning."" (19-year-old female, Quelimane)
	Paternalism (deductive)	If the female partner reports that the male partner wants control family planning or the male partner reports wanting to control family planning	"Yes… my husband forced me [to have an implant]...He's the one who forced me." (18-year-old female, Maganja Da Costa)
Postpartum Contraceptive Use	Current Contraceptive Use (inductive)	Reported current contraceptive use in female partner (or by male partner)	"I put in an implant." (18-year-old female, Maganja Da Costa) "She's using contraceptives, it's an implant." (23-year-old male, Maganja Da Costa)