Study Protocol Statistical Analysis Plan

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Inclusion criteria

1) Married or considers themselves married
2) Living with partner most of the time
3) Living within the selected villages in the last 3 months
4) Age 18 (or an emancipated minor) to 40 for women; age 18 to 50 for men
5) Luganda speaking
6) Not currently pregnant
7) Has no knowledge of infertility
8) Wanting to avoid pregnancy for at least a year (at least one person in the couple)
9) Not using a method of contraception at the moment **OR** only using low-efficacy or ineffective method of contraception (defined as using condom less than 100% of the time, Fertility-Awareness Based methods e.g., counting method, withdrawal method, spermicide, emergency contraception, and sponge)
10) Never used a non-reversible method (male or female sterilization)
11) Has sex in the past 3 months (woman)

Recruitment & Sampling

In each village, members of the Village Health Team (VHT) will assist our research staff in identifying potentially eligible couples. For the couples that we attempt to recruit based on the VHT's referral, the VHT will first independently visit couples' homes to introduce them to the study, and gain permission to return with the research assistant. If permission is granted, the VHT will accompany our research assistant to couples' homes to introduce our research assistant.

If both partners are together during this initial meeting, the research assistant will inform them of the overall study together, but will screen and assess eligibility separately, ensuring that participants are able to answer the eligibility screening questions about fertility preferences and current use of contraceptives in a private setting to ensure confidentiality. Research assistants will be trained in to try to separate spouses in a culturally appropriate and sensitive manner. In cases where the research assistant feels separate screening will not be possible, s/he will attempt to reschedule to come back and conduct the screenings separately. If a reschedule is not possible and screening must happen together, the research assistant will conduct a follow-up phone call or house visit with just the woman to confirm the accuracy of her responses. The research assistant will then obtain written informed consent from the participants. See recruitment script for eligibility screening questions. No identifying information will be collected for eligibility screening. The interviewer will proceed to conduct the baseline questionnaire after obtaining written informed consent for both partners.

If only one partner is present during the initial meeting, the research assistant will proceed with the eligibility screening. If the partner (male or female) is found eligible and interested, the research assistant will ask him/her to refer their partner to the study (either by calling their partner themselves, having the partner call the research assistant or the VHT). The research assistant will conduct the eligibility screening with the second partner over the phone, or will return to the house at the scheduled date and time, and follow the same procedures described above to assess eligibility, obtain informed consent for study participation, and conduct the baseline questionnaire.

If an eligible participant is interested, but their partner declines participation, we will provide a referral to family planning services for a nearby clinic to the interested participant (in both the intervention and control villages to maintain balance between the study arms).

Enrolled couples can also refer other couples to the study (snowball sampling). They will provide the study contact to the referred couples directly, who can choose to contact the study team.

Data collection

Questionnaires

Baseline. After the informed consent process in a one-on-one interview, using a computerized structured questionnaire in the participant's home or another agreed upon location, the Research Assistants will collect demographic information and the measures to assess family planning determinants. Participants can also complete the baseline interview over the phone shortly after enrollment if needed. Total duration ~45 minutes.

~7-month assessment. Research Assistants will conduct a ~7-month follow up with the interviewers using an individual structured interviewer-administered computer-based interview (~45 minutes duration) in the participant's home, another agreed upon location, or via telephone. The 7-month questionnaire will serve as a measure of intervention effects on contraceptive use and relevant determinants of family planning. Total duration ~45 minutes.

~10-month assessment. At ~10-month follow-up the interviewers will conduct an individual structured computer-based interview (~45 minutes duration) in the participant's home or another agreed upon location. Men and women may complete this survey via telephone; however, women must complete a second pregnancy test in-person. The 10-month questionnaire will serve as a measure of intervention effects on contraceptive use, contraceptive continuation, and relevant determinants of family planning. Total duration ~45 minutes (55 minutes for women taking pregnancy test)

**Note: The study protocol originally planned for 3 and 6-month follow-up time points, but the assessment points were extended due to COVID-19 travel restrictions that occurred during the study.*

Process Data

Brief interviews with participants after each session. After each intervention and control session, all couples will complete a brief semi-structured interview (~5 min) to assess acceptability of the intervention content and structure, rating perceived importance and satisfaction with intervention content, and an open-ended question on what they liked and disliked. These brief semi-structured interviews will also include questions to assess any unanticipated negative adverse events occurring because of the intervention (e.g., partner conflict).

Exit interviews with participants post-intervention. Within 3-4 weeks of the pilot intervention, brief semi-structured exit interviews (~15 min) will be conducted with intervention participants (n=70), as well with facilitators (n=2), participating health workers (n=2), and community leaders (n~2-4) to further assess acceptability, feasibility, appropriateness, barriers to implementation/utilization, areas for improvement, and progress on "Family/Community Action Plans." Exit interviews can be conducted in-person or over the phone. See Table 3 for more detail on measures of acceptability and feasibility for intervention content and structure.

Data collection to assess intervention fidelity. Facilitators will follow a fidelity checklist to ensure all steps are completed, which will also be monitored in early dialogues and then randomly throughout the course of the study through direct observation of intervention sessions by research

staff to allow for immediate feedback. Staff will complete a session checklist on activities conducted, number of participants, engagement, and issues encountered including those related to community leader participation (providing immediate feedback to ensure fidelity). In addition, a randomly selected portion (~20%) of the dialogues will be audio recorded, transcribed, and analyzed for fidelity.

Pregnancy test procedures

At the baseline home visit, after consent is obtained from both partners, we will conduct a pregnancy test. Though the eligibility screening questions asks women if they are currently pregnant, we will conduct the test to confirm. The consent form will inform women that if the pregnancy test is positive, they will not be able to continue participation in the study. The pregnancy test will be a Human Chorionic Gonadotropin (HCG) urine test strip, which requires the woman to urinate in a cup (provided by research staff) and immerse the strip in the cup vertically. The woman will be instructed to urinate in the cup by the research assistant and bring the cup to the research assistant afterward and will be given privacy to do so. The research assistant will immerse the strip in the cup and will read the woman her results (~10 minutes later). If the woman is unable to urinate at the time, the research assistant will schedule a time to return to conduct a second test. If the results are invalid, the research assistant will immerse the strip for longer, conduct a second test, or schedule a time to return to conduct a second test. If the pregnancy test is negative (our final eligibility criterion), the research assistant will conduct the baseline questionnaire with each partner separately either in the home or another agreed upon location. The research assistant will ensure that each partner in the couple have full privacy when completing the questionnaire. If they do not, the research assistant will reschedule the interview for another time. During the 6-month follow-up visit, women fill follow these same procedures. The 6-month visit pregnancy test is used to measure change in incidence of unintended pregnancies. The pregnancy test results will be double entered by the research assistant into a KoboCollect data file upon receipt.

Women found pregnant at baseline

If pregnant, the research assistant will inform the woman of the test results alone, unless the woman prefers for them to be delivered with her husband present. The research assistant will then provide brief couples counseling on the importance of prenatal care, having a skilled attendant at birth, and breastfeeding, provide an information sheet with a list of nearby health facilities offering free prenatal care, and a paper referral to the couples' preferred health facility. She and her partner will be withdrawn from the study and informed of their withdrawal.

Participant contact lists

Participants will also be told that any contact information they provide will be recorded on their contact form which will be kept in a locked filing cabinet in a locked room at the clinic. Their contact information will be compiled into a list with other participants for staff to use when they make phone calls, so that they know who to contact. Participants will be made aware that this list will not contain any information regarding any sensitive information collected from them. During the

consent process, participants will be made aware of the potential risks associated with the above-mentioned retention and tracking procedures, including (1) the possibility of breaches in confidentiality of personal and secondary contact information stored in contact information forms; (2) the possibility of the contact list used by staff to be lost when they are making phone calls; and (3) the possibility of breaches in confidentiality resulting from staff contact attempts (e.g., telephone calls). Verification of comprehension of informed consent associated with retention procedures and their respective risks will be accomplished by asking participants to recall central points of the informed consent**.** During this consent process, participants will be able to ask the research assistant any questions that they have regarding the retention procedures. This process will verify understanding of informed consent, will clarify points of confusion, and will ensure that the potential risks of participation associated with the retention-promoting procedures are understood and accepted by consenting participants prior to participation.

Data management

Qualitative data

Audio recordings of all qualitative data will be transferred to a password protected computer. All focus group discussions, key informant interviews, and qualitative exit interviews will be transcribed and translated into English and entered into a software analysis system (Atlas.ti). Electronic audio recordings of individual and group counselling sessions will be transcribed within 6 months of the session and the audio recordings will be destroyed once the information from the recordings is written down and double-checked for accuracy.

Quantitative data

Questionnaires. Data for the baseline, follow-up questionnaires will be entered in real-time while the interviewers are conducting the interviewer-administered CAPI questionnaires (using KoboCollect software). Using the KoboCollect system also eliminates the possibility of any out of range responses and therefore, data cleaning is not necessary. Data collected using Kobo is easily exported into SPSS and other statistical programs for analysis.

Clinic record abstraction. A research assistant will extract data from medical charts and enter it into a database identified only by study ID number. Extracted data will include date of family planning visit, and type of contraceptive method received. Clinical record data will be double entered by the research assistant into a KoboCollect data file upon receipt. The double entered data will be checked and any discrepancies will be corrected by double checking the clinic records, and by comparisons with the laboratory report.

Pregnancy test data entry. The pregnancy test results will be double entered by the research assistant into a KoboCollect data file upon receipt.

Data safety monitoring plan

The proposed study will conform to rigorous monitoring procedures, standardized reporting of adverse events using Event Report Forms, regular review of the study by the joint-Principal Investigators (PIs), Drs. Sileo and Kiene, and review of the study by a Data and Safety Monitoring Board (DSMB).

The PIs, Drs. Sileo and Kiene, Ms. Christine Muhumuza, and research staff, will ensure appropriate: (1) conduct of the informed consent process (e.g., that informed consent is obtained before proceeding with study procedures and properly stored), (2) enrollment of study subjects, (3) collection and analysis of data, (4) implementation of study procedures to ensure consistent monitoring of subjects for possible adverse events, (5) review of adverse events and reporting to the DSMB and IRB, and (6) maintenance of the privacy and confidentiality of study subjects. The PIs maintain ultimate responsibility for the project and for the safety of study participants.

Dr. Sileo and Ms. Muhumuza will be responsible for meeting with the research team on a regular basis (weekly, either in person or by conference call) to review the progress of the study and address any human subject issues that occur. These discussions may involve adverse event prevention measures, recruiting of appropriate study subjects, research staff training on protection of human subjects, as well as occurrence of adverse events, unexpected incidents, or protocol problems. The joint-PIs and subcontract PI will meet with the research assistants regularly to go over the progress of the study and communicate any issues or adverse events to the joint-PIs. Ms. Muhumaza will compile reports on this information to submit to the PIs and Data and Safety Monitoring Board (DSMB) for review.

Data Safety Monitoring Board (DSMB)

The DSMB will consist of a committee of experts responsible for reviewing clinical trial data on an ongoing basis to ensure the safety of study subjects and validity and integrity of the data. Members will be independent, with no vested interest in the outcomes of the present study. The board will consist of three members, at least one from Uganda and at least one from the U.S., unless the UTSA or MakSPH institutional review boards recommend a larger committee based on their assessment of the level of risk of the present trial. At a minimum the members will include (1) expert(s) in the clinical aspects of the disease/patient population being studied; (2) one or more biostatisticians; (3) and investigators with expertise in current clinical trials conduct and methodology.

The DSMB will review the study to approve the initial protocol before data collection begins, and every 3 months throughout the duration of data collection activities. We anticipate data collection activities will be completed over an 8 months period, thus the DSMB is expected to meet twice during this period. Before each DSMB meeting, Ms. Muhumaza will provide the DSMB with a report containing (1) study progress such as accrual, baseline demographic characteristics, and other general information on study status, and (2) any confidential data on study outcomes, including safety data. This information will allow the DSMB to review and assess the safety of participants and the validity and integrity of the data. Meetings shall be closed to the public because discussions may address confidential patient data, or present unblinded data. Meetings

will be convened as conference calls. An emergency meeting of the DSMB may be called at any time should questions of participant safety arise. The DSMB may request the presence of study investigators at such meetings. A formal report from the DSMB will be supplied to the PIs within 6 weeks of each meeting. Each report will conclude with a recommendation to continue or to terminate the study. This recommendation shall be made by formal majority vote. Any recommendation to terminate the study will be transmitted to the PI, IRB, and NIH as rapidly as possible via a letter from the DSMB Chair/Administrator to the PI for distribution to the institutional official, sponsor, and the local IRBs.

Monitoring Intimate Partner Violence (IPV)

Though we expect the risk of adverse events resulting from participation in the intervention to be low, since we are working with couples and facilitating discussions around sensitive topics, such as family planning and gender norms, we have developed procedures to closely monitor participants in the couples' intervention. The implementation of these procedures will ensure any unanticipated adverse events related to violence or relationship conflict are identified and addressed immediately. First, our baseline data will assess participants' history of experiencing and perpetrating intimate partner violence. We will use this data to identify couples who report a history of violence, so that intervention facilitators can closely monitor those couples, and pay special attention to issues of violence in the intervention sessions to minimize the risk of conflict arising between couples. In addition, after each couples' session, men and women will separately complete a brief questionnaire to collect process data on the feasibility and acceptability of the intervention. In addition to questions on feasibility and acceptability, this questionnaire will include questions to assess if the intervention had any negative consequences on couples' relationships, either during the intervention itself, or since the last intervention session, whether at home or elsewhere. Items will include a modified 3-item version of the Conflict Tactics Scale to assess experience of emotional, physical, and sexual conflict since the last intervention session. Participants will be asked about the frequency of being the recipient of each type of conflict by their partner, as well as the perpetrator of each type of conflict. The questionnaire will also include an open-ended question to probe further on the occurrence of abuse if any is reported. The responses to this questionnaire will be reviewed immediately by the intervention facilitators, as well as a research assistant. Any indication of potential abuse or conflict resulting from the intervention, whether verbal or physical, will be reported immediately to the Investigators, and follow the plan for reporting adverse events (described below) and a protocol to minimize the risk of future adverse events, determine the safety of the participants' continued participation in the study, and refer the couple to support services (see "Protection of Human Subjects" section) for more details.

Adverse events

The study is of minimal risk and therefore no serious anticipated adverse events are expected. Serious unanticipated events will be reported within 48 hours to the UTSA Human Investigation Committee and the Makerere IRB, the co-investigators listed on the protocol, and NICHD.

The joint-Principal Investigators (Drs. Sileo and Kiene) will conduct a review of all adverse events (serious and non-serious) every month during a scheduled meeting and keep a log of all events. They will evaluate the frequency and severity of the adverse event(s) and, in conjunction with the UTSA and Makerere IRBs, determine if modifications to the protocol or consent forms are required. A report to the three institution's IRB will be made when re-approval for the protocol is sought on a yearly basis, or more frequently if deemed necessary by the PIs based on the number and severity of adverse events. The summary will include the number of participants enrolled in the study and a summary of the adverse events to date (including relation to study and severity).

The joint-PIs, in conjunction with UTSA and Makerere IRBs, will be responsible for monitoring the data and conducting performance safety reviews at a minimum of every 3 months. The Principal Investigators, and the two institution's IRB, have the authority to stop or modify the study at any time. During the review process, the Principal Investigators will monitor and evaluate whether the study should continue unchanged, require modification, or close to enrollment.

Discontinuation/withdrawal of participants from intervention

In this study, each participant has the right to withdraw from the trial at any time. In addition, the Investigator may discontinue a participant from the trial at any time if the Investigator considers it necessary for reasons such as; an adverse event that requires discontinuation of the intervention or results in inability to continue to comply with study procedures. The reason for withdrawal will be recorded in the Procedures for Recording Adverse Events (CRF).

Resource/Data Sharing Plan

Even though data sharing is not required since this project does not request >$500,000 in any project year, we plan to share our data within our institutions. This project involves the collection of formative qualitative and quantitative baseline data in the first year and the collection of quantitative baseline data and data evaluating our intervention in year 2 in the Butambala Health sub-District of Uganda. In general, it is difficult to fully de-identify qualitative data and difficult to interpret without an understanding of the context. In addition, there will be Luganda terms in the text. As a result, we will not make these data available for data sharing. In addition, our intervention and control arm's data draws on medical record data that are the responsibility of the Butambala Health sub-district in Uganda. These data will only be available as included in the data set created from the quantitative assessments (baseline, follow-up assessments). These data will be made available under the following provisions:

(1) The data will be fully de-identified

(2) A period of three years elapses after the completion of the project to allow the PIs the opportunity to publish major findings

(3) Access to the data will be limited to researchers and their students at the three collaborating institutions: Yale University, San Diego State University, and the Makerere University School of Public Health (MakSPH)

Other Permitted Access to Data

Direct access will be granted to authorised representatives from the Sponsor (NIH), host institutions and the regulatory authorities to permit trial-related monitoring, audits and inspections.

Training of the RAs/Facilitators

Training of research assistants

To collect baseline and follow-up interview data for the intervention experienced research assistants/interviewers will be hired for the purposes of the study. These individuals will be trained in the study procedures by one or more of the investigators. Research Assistants/interviewers will undergo a two-day training in the study procedures. They will also be actively involved in the piloting of training tools, which will serve as additional training. Throughout the duration of the study, the Investigators will monitor data collection procedures and the quality of data received, and conduct refresher trainings as needed. Clinic staff will also be oriented to the study and the study procedures by the investigators.

Training of intervention facilitators

Group facilitators experienced in the delivery of behavioral interventions and health workers who will deliver the intervention will undergo a 5-day curriculum-based training of the intervention content using role playing and simulated group discussions led by Ms. Muhumuza and Dr. Sileo. Community leaders selected to facilitate session 3 discussions will participant in a 1-day training specific to their role. Training will emphasize the principles of voluntarism and informed choice with respect to contraceptive use, the role of gender equity in family planning, managing group dynamics, facilitating transformative dialogues without creating conflict, and identifying and minimizing adverse outcomes.

Data Analysis Plan

We assessed baseline equivalence between the study arms on demographics using Generalized Estimating Equation (GEE) models in SPSS v. 28, which account for dependence from repeated, dyadic data. We tested intercorrelations between variables that differed ($p < 0.10$) between arms at baseline, or variables deemed theoretically relevant (i.e., age, number of children), to identify covariates. Based on these analyses, all models controlled for religion (based on differences in baseline equivalence) and age. The time by intervention interaction on contraceptive uptake (main outcome) at follow-up was tested using GEE with a logit link distribution (couple the unit of analysis). We report unintended pregnancy descriptively (underpowered but included for feasibility). For all secondary outcomes, GEE was used (linear for continuous outcomes and logistic for binary outcomes), with time and gender specified as within-subject effects. Unstandardized betas (b) and standard errors (SE) are reported for continuous outcomes and adjusted odds ratios (AORs) and 95% confidence intervals (CIs) are reported for binary outcomes.