Title:

rPlan Multimedia Dual Protection Intervention to Reduce Health Disparities

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miPlan: A multimedia dual protection intervention to reduce health disparities

Detailed Protocol

1. Background

This research aims to extend previous studies which have used health interventions with digital media to provide pregnancy prevention counseling to develop and assess the acceptability and efficacy of ***miPlan***, a three-part intervention that includes a precounseling app that promotes **dual protection** (STI and pregnancy prevention), motivational interviewing-informed counseling, and concomitant printed educational materials. The research will proceed in two phases. In Phase I, we will assemble a 10-member stakeholder advisory team to enhance the *PreCounselor* app to focus on dual protection, train reproductive health counselors in motivational interviewing, and create concomitant printed educational materials. In Phase II, the feasibility, acceptability, and effectiveness of the intervention will be assessed among young women (ages 15-25).

Disparities in STI/HIV and Unintended Pregnancies among Young African American Women

Young AA women (15-19 years) experience significant reproductive health disparities, with a chlamydia rate nearly six times and a gonorrhea rate sixteen times those of their white counterparts.[9] If untreated, these infections can lead to infertility or life-threatening ectopic pregnancy.[9] Further, AA women have a 1 in 32 lifetime chance of contracting HIV.[10] Nationally, 49% of all conceptions are unintended, with high rates for African Americans (AA) of all ages (67%) and for women ages 15-19 (82%).[2] Unintended pregnancy is associated with abortion, delayed or no prenatal care, and multiple increased health risks for infants and children.[11] Recognizing the significant inequity in unintended pregnancies and STI/HIV rates among young AA women is an important first step to creating effective sexual and reproductive health interventions.

Limited Use of Highly Effective Contraceptive Methods

Most contraceptive methods are highly (>90%) *efficacious* but are prone to user error, compromising *effectiveness* in real-world settings. 48% percent of women with unintended pregnancies report using contraception during the month of conception.[12] Most young women rely on short-acting or coitally-dependent methods like oral contraceptive pills (OCs) or condoms.[13] Half of young women report imperfect OC use, with about 25% missing ≥2 pills in a cycle.[14] However, long-acting reversible contraceptive (LARC) methods like the intrauterine device (IUD) require few use behaviors while providing *effective* (>99%) and *long-lasting* (3-10 years) protection against pregnancy.[15] Yet, <7% of women using contraception in the United States (US) use LARC, with rates lowest among those at highest risk of unintended pregnancy.[13]

Need for Novel Dual Protection Interventions

The significant reproductive health disparities of young AA women demonstrate the need for novel interventions that promote dual protection and account for their unique reproductive health challenges and life contexts. The few clinic-based interventions designed to increase dual protection have largely been unsustained or have failed to result in statistically significant effects.[16-18] Young women receiving a computer-based, tailored intervention reported increased dual method use, but no change in STIs and unintended pregnancies compared to controls.[19] Reanalysis of the data showed 32% initiated dual method use, but only 9% sustained use.[20] A video counseling intervention for AA and Latino female adolescents increased condom use at three months post-intervention, but not at 12-month follow-up.[21] However, we should remain hopeful about reducing such disparities. In a large-scale study, when barriers to all contraceptive methods were lowered and LARC was presented as the optimal method, rates of LARC uptake surpassed 65% and pregnancy and abortion rates declined.[15,22] While efforts have traditionally focused on improving condom use, there is evidence that youth rely on many dual protection strategies.[23] Thus, interventions must address multiple types of "dual protection".[24]

Need for Scalable, Brief Interventions

Brief, inexpensive, practical, and theoretically-based interventions may hold promise for reaching large numbers of people. A growing body of research[25-27] suggests that brief interventions relying on more than just information can be successful.[28-33] Interventions with strong behavioral models, focused information, and opportunity to address potential barriers to change tend to report stronger effects.[28,29]

Importance of E-health, Health Information Technology and Counseling Aids

Interactive multimedia programs present a novel platform for delivering interventions.[34] Digital media provides an opportunity to scale interventions and reach the broad population of youth necessary to reduce STI rates. Tailored, theory-based digital interventions have been effective in smoking cessation,[35] reducing repeat births among low-income AA adolescent mothers,[32] promoting adherence to antiretroviral medications,[36] and increasing awareness of diabetes complications.[37] Users of a touchscreen computer intervention were significantly more likely to choose highly effective contraception.[38] Multiple programs have successfully taken advantage of clinic wait times[37,39-41] without obstructing patient flow. HIV-positive users of a counseling tablet found it reduced social bias, promoted honesty in discussing sensitive topics, and promoted privacy.[42]

Key Theories and Approaches Informing this Intervention

The **Transtheoretical Model** (TTM) and its Stages of Change paradigm posits that in changing behaviors, individuals progress through sequential stages of *Pre-contemplation, Contemplation, Preparation, Action* and *Maintenance*. Transition between steps requires a core set of change processes.[49] Women seeking contraception are most likely in *Pre-contemplation* or *Contemplation* stages for adopting dual method use including LARC. For *Pre-contemplation*, the

key change process is enhancing awareness. Video vignettes that present co mmon behavioral, normative, and control beliefs, constructs from the **Theory of Planned Behavior** (TPB), can address acquisition of a new behavior. For those who are in or move to the *Contemplation* stage, the key necessary change process is to "tip" decisional balance. **Motivational interviewing (MI)** teaches that an efficient and effective strategy for helping to "tip" the decisional balance is to explore and resolve ambivalence, something not typically used in less effective counseling processes, which tend to impose a solution. We will employ elements of motivational interviewing, which we term **MI-informed counseling**, including: collaborating as partners, empathic understanding, autonomy support, and self-efficacy support. Consistent with our conceptual model, a **Risk Reduction** framework for dual protection is incorporated. LARC with condoms is the optimal option, but it is not the only option. Risk reduction frames prevention behaviors along a continuum rather than in binary terms, recognizing opportunities for incremental behavior change, especially when behaviors are suboptimal.[50] Thus, STI/HIV messages will also center on behaviors including condom use, partner negotiation, limiting the number of sexual partners, STI testing after unprotected sex, avoiding alcohol and drug use, and use of expedited partner therapy. These behaviors reduce risk even among condom users.[24] Finally, both women and men will be portrayed in videos to ensure that the educational messages are patient-centered, salient, authentic, and relevant. **Human-Centered Design (HCD),** a design approach recently applied to health care, ensuring that interventions meet the needs of the community of users, **will be used to create a usable, sustainable intervention**.[51] In HCD, the designer and end-user collaborate to create solutions in an iterative process of rapid prototyping with key stakeholder participation. Resulting interventions are based on available technology, address true barriers, and are matched to a realistic understanding of behaviors, skills, and informational needs. We will use HCD best practices such as iterative low-fidelity prototyping and multiple course corrections before a final solution is achieved.

2. Hypotheses

We hypothesize that post-intervention, patients using *miPlan* will report:

H[1] a significant increase in contraceptive continuation and condom use

H[2] significantly fewer episodes of unprotected sex

H[3] significantly greater levels of self-efficacy and confidence for dual protection

H[4] significantly improved sexual health attitudes regarding STI/HIV prevention behaviors

H[5] significantly fewer negative experiences with condoms and fewer condom use errors and problems.

Ultimately, *miPlan* has the potential to significantly impact racial and ethnic health disparities in STI/HIV and unintended pregnancy.

3. Methodology

Aim 1: Develop the *miPlan* intervention by (1) enhancing the pretested *PreCounselor* app to focus on dual protection, (2) training reproductive health counselors, and (3) creating concomitant printed educational materials.

Convene a Stakeholder Advisory Team. A 10-member Stakeholder Advisory Team of young **women** (n=4), young **men** (n=4), and **clinic staff** (n=2) will be convened to assist in *miPlan* development, followed by quarterly meetings throughout the project. Young men will help capture the dyadic nature of pregnancy and STI prevention, particularly condom use *motivations, behavioral intentions, and negotiation*, framing open dialogue across genders as essential to reproductive health. Men's input will be critical in identifying salient decisional balance/self-efficacy beliefs regarding target behaviors and for developing relevant STI/HIV prevention videos for *miPlan*. The Advisory Team will ensure that *miPlan* reflects the experiences and needs of participants. Members will receive $300 over 2 years.

Develop the MiPlan *app*. We will rely on our extensive experience creating counseling apps with clinic populations using HCD.[48] Prior to committing resources to app development, we will "mock up" *miPlan* with the Advisory Team, relying on the many assets already created for *PreCounselor* (e.g., graphics, text, video).[51] Early paper and pencil sessions help to develop algorithms for dual protection decision-making, app pages, and educational content. We then "walk through" multiple app scenarios, role-playing users at different stages of change for dual method use and various dual protection strategies. We will iteratively revise the elements with each round until members are in agreement with the content and form. Next, a tablet with voice recordings and Powerpoint slides will simulate the user experience. We will recruit users in the clinic waiting room (n=7) to use the app prototype in 20 minute sessions, filming their hands as they use it, taking notes as they navigate aloud, and making changes in response to their feedback, allowing for immediate course corrections in the user session (compensation=$20). We anticipate 5-7 sessions to finalize design decisions. We will create additional videos focusing on STI prevention behaviors by recruiting youth who are successfully using the method, asking them to address common behavioral, normative, and control beliefs (TPB constructs) in their testimonials. We envision that at least one of these videos will include young men. The final elements will be programmed as the *miPlan* app.

Develop Educational Materials. We will create short paragraphs addressing condom use, incorporating up-to-date, **evidence-based** contraceptive and STI guidelines.[45,46,54] Materials will avoid medical jargon, use short sentences, and focus on general and method-specific information and strategies to build self-efficacy and prevent relapse. They will feature the same images as the *miPlan* app to reinforce counseling. The Advisory Team will review and recommend changes to materials and we will assess readability. Dr. Holmquist has expertise in medical and sexuality education and curriculum development and will lead this activity.

Training in Motivational Interviewing (MI)-informed Counseling. We will train two research assistants (RAs) to serve as contraceptive counselors. Separate counselors will ensure swift

recruitment and minimize clinic interruptions. Training will include how to use the *miPlan* app, identify and address ambivalence, and support strategies for managing anticipated barriers. Dr. Quinn, an experienced MI counselor, will oversee training, providing didactic presentations on core concepts of the TTM, including stages and process of change and decisional balance. Dr. Holmquist will oversee training related to condoms and contraceptive methods.

Aim 2: Conduct a pre/post feasibility, acceptability, and effectiveness assessment of *miPlan* to examine improvement in dual method use, enhancement of contraceptive adherence and continuation, increase of condom use, and decrease of STI/HIV infection.

Recruitment and Enrollment. All research activities will take place at the DCAM at the University of Chicago and select Planned Parenthood-IL clinics(Austin, Englewood, and/or Roseland).. We will pre-test the app and study procedures with 5 participants (compensation=$50), following the protocol planned for the pilot study. At their clinical visit, participants who meet the inclusion criteria (n=100) will be referred by clinic staff to a trained on-site RA, who will explain the study and complete the informed consent process. Inclusion criteria are: (1) Being AA female and sexually active with a male partner(s) within the past 6 months; (2) Age 15-25 years; (3) Initiating contraception; (4) Not currently pregnant or intending pregnancy within the next 6 months; (5) English speaking; and (6) Not currently using LARC. As Illinois law ensures the rights of minors to receive confidential reproductive health care without parental consent, we will seek a waiver of parental consent for participation of those 15-17 years old.

Pre-Intervention Baseline (T1) Procedures. Participants will complete a 10-15 minute questionnaire on the *miPlan* app (See appendices). The RA will provide a brief orientation to the *miPlan* app. After viewing *miPlan*, participants will be guided through a MI informed conversation using a worksheet to document the discussion on contraceptives knowledge and usage. The completed worksheet will be given to the participant and a copy will be kept for the participant's records. (10 min). The participant will receive educational materials and a strategies worksheet to discuss with their clinician. The participant will also be given an STI test. Participants will be compensated $30.

Post-Intervention (T2) Procedures. At 6-weeks post-enrollment, participants will complete a 15-25 minute phone survey to gauge dual method use, contraceptive adherence/uptake, frequency of unprotected penile-vaginal/anal intercourse (PVI/PAI), and risk reduction behaviors. Participants will be compensated $20.

Follow-Up (T3) Procedures. At 3 months post-enrollment, participants will complete a 15-25 minute in-clinic survey to gauge maintenance of dual protection behaviors, contraceptive adherence/uptake, frequency of penile vaginal intercourse/penile anal intercourse, risk reduction behaviors, decisional balance/self-efficacy, and an STI test. Participants will receive $40. We will also conduct a 3-month retrospective chart review to capture interceding visits (e.g., initial contraceptive method selection, method switching, etc.) and diagnoses (e.g., pregnancy, STI/HIV). Participants unable to come in to clinic for their followup visit or who do not wish to come to clinic will be offered an at-home STI screening kit, to be mailed to the address they

provide. Participants who wish to be sent a kit will be mailed a endo-cervical screening kit, via USPS priority mail, with pre-paid postage and instructions for using the administering the self swab to themselves and packaging and mailing the completed kit back to Ci3. No identifying information will be included in the mailing, and all costs with mailing and processing will be paid by Ci3. All participants will be offered the at-home screening option upon reaching their three month follow-up event, and can complete the survey over the phone or online.

4. Duration

We are requesting IRB approval for a portion of Aim 1 to develop and pilot test the miPlan app and Aim 2 which cover months 3-21 of the overall study.

5. Location

The study will be conducted at the Duchossois Center for Advanced Medicine (DCAM) at the University of Chicago . The DCAM is home to adult primary and specialty clinics, pediatric specialty clinics, and outpatient diagnostic and treatment facilities of the University of Chicago Medicine. The will also be additional sites at Planned Parenhood-IL clinics, Austin, Englewood, and/or Roseland.

6. Special Precautions

The primary risks are loss of confidentiality and potential discomfort associated with answering sensitive questions about STIs, HIV, and sexual risk behaviors. All participants will be assigned a unique study identifier. Once all data has been collected, identifying subject information (including name) will be stripped from the database and from transcripts of focus group and in-depth interviews Informed consents with the subjects' names will be stored at the University of Chicago and only accessible to designated research staff. Consent forms will be stored in a locked filing cabinet in a locked office at the University of Chicago. Reports, manuscripts, and presentations will never include identifying information. With respect to potential discomfort associated with answering sensitive questions, subjects will be informed that they can skip any question they do not want to answer without penalty and that they can opt out of the study at any time without penalty. Participants are informed of these protections in the consent forms and all relevant study documents.

7. Experimental Controls

Not applicable. This is a pre- and post- intervention

8. Type and number of subjects

During Aim 1, we will recruit users in the clinic waiting room (n=7) to use the app prototype in 20 minute sessions, filming their hands as they use it, taking notes as they navigate aloud, and making changes in response to their feedback.

During Aim 2, we will pre-test the app and all study procedures with 5 women. In the pre- and post-intervention, we will recruit 100 young women (ages 15-25) from the waiting room of a gynecology clinic at the University of Chicago and select Planned Parenthood-IL clinics.

9. Statistical Analysis

Feasibility & Acceptability: Descriptive statistics will be used to analyze the proportions and central tendency for satisfaction, helpfulness, appropriateness, and usefulness of *miPlan*. *Effectiveness:* Outcome variables will be measured in the following ways: Chi-square or Fisher's Exact Test (categorical variables); *t* test and Mann-Whitney U test (continuous variables); and multinominal logistic and linear regression models. Multinomial logistic regression models will be used based on multiple categories for dual method (e.g., use of oral contraceptive with condoms; implant with condoms; or IUD with condoms). Linear regression and probability models will be used with the categorical dual method collapsed (e.g. any dual method). Covariates will be initially screened for potentially significant relationships with variables using bivariate testing and those attaining a $p<.20$ will be assessed in multivariable analyses. Because outcome variables may have missing values due to attrition, primary data analyses will be performed: (1) with only complete cases (women for whom there were no missing values) and (2) using multiple imputation.[59] Sensitivity analyses will be performed to address extreme outlying variables. We will conduct comparisons of demographic and baseline attributes among drop-outs versus retained participants.

10. Risks and Benefits

Potential risks consist of the actual interview data collection process and potential breaches of confidentiality Participants may feel embarrassed with some of the questions that deal with sexual health and sexual behavior. However, participants will be allowed to opt out of the study and to not respond to questions they are uncomfortable with without any penalty. Study records that identify the participant will be kept confidential; however there is a risk of loss of confidentiality. Participants will be informed of these risks, protections against loss of confidentiality, and their rights to skip any question and to withdraw from the study at any time in the consent forms and all relevant study documents. In addition, there is potential risk to confidentiality if a 15–17 year old reports sexual abuse or if any participant reports suicide risk or intent to harm someone else during any study visit. All university employees are required to report suspected cases of abuse or neglect and we are ethically bound to address issues of suicide risk. All participants are told in the consent that statements of potential harm to self or others require reporting. We have extensive experience dealing with this issue, and specific procedures are in place (described in detail below) for referrals and strict confidentiality of reports. We will take the utmost caution to protect the confidentiality of responses and have detailed these procedures below.

The potential benefits of this research far outweigh the risks. First, African American women are the group most affected by unintended pregnancy and STIs. Despite these factors, there are few evidence-based interventions that have been specifically developed and tailored for the dual protection needs of young African American women. We propose to develop and pilot test an innovative mobile app-based intervention to prevent/reduce STI and pregnancy-related risk behaviors. The intervention has the potential to reach large numbers of young women. Women who participate in the study may benefit from receiving information about pregnancy and STI prevention strategies that may not be provided in standard of care or available through other mechanisms (e.g., sexual health education, STI clinic information, etc.). Possible risks (i.e. discomfort answering questions, potential confidentiality breaches) are outweighed by the new knowledge gained regarding the potential of an app-based intervention to reduce STI/pregnancy risk among young African American women. We have adequate safeguards to protect against these risks and will alert the University of Chicago IRB of any problems.

11. Monitoring of Safety

The PI is responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews at the specified frequency. The Research Manager will oversee day-to-day compliance. This protocol presents minimal risks to the subjects and adverse events or other problems are not anticipated. The PI and Research Manager will be responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews at regular intervals which must be conducted at a minimum of every 6 months (including when re-approval of the protocol is sought). During the review process, the PI and Research Manager will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment. The PI, IRB and the Research Manager will ensure that any deviations from the protocol or safety concerns are reported according to institutional guidelines. Data and study risk will be assessed throughout the study.

12. Payments

During Aim 1, clinic waiting room users (n=7) who will use the app prototype in 20 minute sessions will receive $20 compensation for their participation.

During Aim 2 of the research, pre-test participants (n=5) will receive $50 for their participation. Pre- and post-intervention participants will receive up to $90 (Time 1-baseline: $30; Time 2- 6 weeks: $30; Time 3- 3 months: $30) for participating in the intervention.

13. Informed Consent

Study coordinators and designated research staff will obtain written consent from all participants. Research staff will describe the study procedures and anticipated risks and benefits to ensure the study participants understand the study. We will document that the informed consent process occurred. One copy of the informed consent will be provided to the subject and one copy will be placed in the in the subject's research files. Participants will be reminded that their participation is completely voluntary and they are free to withdraw from the study at any time. All subjects will be re-consented and sign new consent forms if there are any changes to the informed consent form (i.e. something occurs that changes the risk/benefit ratio of the study). Written consent will be obtained at the beginning of the prototyping, pilot testing, and intervention session s and the study will be explained in detail and before the each phase begins. In all instances, participation in the sessions (prototyping, pilot test, and intervention) will occur immediately after the consent is obtained.

Consistent with our previous studies in this population, we do not require parental consent for study enrollment. Parental consent may decrease participation rates because *some* young women will fear that their personal information may be disclosed as a result of participation. In addition, Illinois law ensures the rights of minors age 13 years or older to receive confidential sexual/reproductive health care (including STI/HIV testing, drug or alcohol abuse counseling, etc.) without parental consent. That being said, there may be some participants who fear parental consent. The nature and scope of the proposed research do not pose more than “minimal risk” to participants (45 CFR Part 46.102): “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” To compensate for waiver of parental consent, participants receive a

formal individual assessment of capacity to consent to ensure their understanding of study goals, procedures, and risks from disclosure of sensitive information. Consistent with national policy recommendations from the Society for Adolescent Medicine, requiring parental permission for the proposed study would have a number of possible negative effects, including: (1) reducing the validity of the findings by effectively eliminating potential participants unwilling to share permission forms with their parents/guardians; and (2) adding little in the way of actual subject protection, given the minimal risk of study participation.

Both study participants and parents are informed that the PI and/or research staff is required by Illinois law to report any self-reported or suspected incidents of child abuse or neglect. These will be reported to the Illinois Department of Children and Family Services (IDCFS). As the mandated reporter, the PI will initiate this procedure, following the university guidelines on these types of incidents.

Therefore, the proposed research protocol will seek a waiver of parental consent from the University of Chicago IRB. All consent forms will be securely stored in a locked filing cabinet in a locked office at the University of Chicago.

14. Confidentiality

Only the principal investigator and the immediate research staff will have access to the raw data. No one outside of the institution will have access to the data. All data will be stored on secure network servers that are backed up nightly and password protected.

15. Bibliographic References

Please see attached

16. Recruiting Methods

Participants in the iterative design process, pre-test and pilot will be recruited by research staff from the clinic waiting room at University of Chicago and select Planned Parenthood-IL clinics. A qualified member of the research staff will conduct eligibility screening to ensure participant eligibility. This member of the research staff will also work with clinicians in order to identify potentially eligible patients who have scheduled appointments during the recruitment phase of the study. These patients will be telephoned in advance and informed that they may be able to participate in the study during their medical visit. Eligible participants will be consented and enrolled. Research activities will take place at the University of Chicago and select Planned Parenthood-IL clinics. The informed consent process will inform the participant that participation is completely voluntary and that a decision not to participate will not affect her care at the University of Chicago or Planned Parenthood.

17. Primary Physician Notification

Not Applicable

18. Interdepartmental Coordination

Not Applicable

19. Pregnancy Test

Not Applicable

20. Rationale for Exclusion

Because the present study is focused on preventing STIs and pregnancy among young African American women, we will exclude non-African American subjects. We also will exclude any prospective participant with a cognitive deficit that precludes providing informed assent/consent.

21. Medication Infusion

Not Applicable