Official Title: Contraceptive Awareness and Reproductive Education

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

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Study Overview

Nearly 5% of reproductive-age women experience unintended pregnancy each year and this rate is significantly higher than in other developed countries.[1] More than half of all new sexually transmitted diseases (STDs) reported in 2020 were among young people ages 15-24 years old, and among sexually active young women, only 47% reported using a condom during their last intercourse.[2] Unintended pregnancies are highest among low-income women, women ages 15-24 years and women of color.[1] Youth in justice, mental health and alternative school settings all appear to be at increased risk for unintended pregnancy and STIs,[3-5] and this may be related to the overlap in youth entering and exiting these systems.[6-8] Although young women in alternative school, justice and mental health settings are at increased risk to engage in sexual risk-taking, relatively few interventions have been developed for them.

Behavioral intervention may be effective in reducing sexual risk and should include information on sexually transmitted infections (STIs), motivating commitment to safer sex, training in condom use and partner communication, and problem-solving.[9] Motivational Interviewing (MI) is well-suited to reduce risky sexual behaviors in youth as it engages, is directive, elicits youth motivations for reducing risk, and attends to creating a change plan as appropriate; however, further work is needed to refine and test MI for sexual risk-taking behaviors.[10] Meta-analyses[11-12] indicate MI may be particularly useful for minoritized populations; however, as a treatment for risky sex, more study is needed, including addressing the impact of poverty.[10]

Study Objectives

Aims: To evaluate in a randomized clinical trial the degree to which Computer Assisted Motivational Interviewing (CAMI) compared to Didactic Educational Counseling (DEC) will:

1. **Increase the initiation of highly effective contraceptives in a high-risk juvenile population.** Hypothesis: CAMI will increase the initiation of highly effective contraceptives in girls more than DEC. The **primary outcome** is initiation of a highly effective (e.g., hormonal) contraceptive method. This will be measured using calendar-assisted self-report.

2. **Increase the continuation of highly effective contraceptive use at 3, 6, and 9 months.** Hypothesis: Girls randomized to CAMI will be more likely to continue the use of highly effective contraception at 3, 6, and 9 months after CAMI intervention compared to girls randomized to DEC. The **primary outcome** is continued highly effective contraceptive use at 3, 6, and 9 months. This will be measured through calendar-assisted self-report. The **secondary outcome** is pregnancy as documented by a urine pregnancy test at each follow-up visit.

3. **Decrease unsafe sexual activity.** Hypothesis: CAMI will decrease unsafe sexual behavior more than DEC. The **primary outcome** is an incident STI after a negative baseline test. The **secondary outcome** is intercourse that is poorly protected against STIs at 3, 6, and 9 months as determined by calendar-assisted self-report.

Study Design and Methods

Recruitment.

Participants were recruited from the RI Juvenile Probation Department (JPD), RI group homes and alternative schools, Job Corps of Rhode Island and Community Mental Health Centers. Girls between the ages of 14 to 21 at each of these sites were approached for recruitment. Girls who were interested in participating were provided further detail, and inclusion and exclusion criteria were reviewed. When eligible and willing to participate in the study, the informed consent process was completed (study explained, consent form read to the individual, questions answered) and forms signed. Locator information was obtained, and consents signed for tracking.

Assessment and Randomization.

Participants were randomized to either DEC or CAMI, and a 30- 45-minute computer administered questionnaire is provided to both groups. When randomized to CAMI there were additional questions on computer and printed information made available to assist the counselor (the MI intervention includes computer feedback on personal risk for pregnancy and STI based on past reported behaviors and planned behaviors). The counselor then administered CAMI or DEC according to randomization. Urine samples for Trichomoniasis vaginalis, C. trachomatis and N. gonorrhoeae will be obtained as well as a urine sample for a pregnancy test. *A second session of CAMI (with negotiation skills training and addressing barriers to services use)* or DEC according to randomization, was administered at the 3-month follow-up visit following the assessment. Follow-up occurred at 3, 6, and 9 months following initial contact and occurred in the community or at a Probation office in private.

Interventions.

CAMI and DEC. The baseline assessment took place on the computer prior to both interventions. It is designed to assess baseline risk behavior and predictive measures. The computer assessment is slightly extended in the CAMI intervention and is designed to assist with MI. The stages of change are utilized during CAMI to assist the counselors. Progression in stages of change will be measured and compared across the two intervention groups. Pregnancy intentions were fully explored and anyone expressing ambivalence or little interest in highly effective contraceptive use were invited to participate in counseling regarding the risks of teen pregnancy.

CAMI. CAMI was composed of two 60-minute sessions of tailored MI counseling occurring at the enrollment study visit, and at 3-month follow-up. CAMI, which is based on MI, employs a directive, client-centered counseling approach to enhance motivation to change by having the client clarify and resolve ambivalence and commit to changing behavior. Session 1 began when the participant finished the computerized assessment and segues into an additional 10-minute computer segment that included a pregnancy and STI risk assessment. The risk assessment and the feedback on contraceptive and sexual behaviors were available on the computer but were also printed out for later review by the counselor. Counselors reviewed the personalized assessment with the participant and discussed sexual and contraceptive history, pregnancy and STI risk level, and substance use over the past 90 days to identify risky behaviors for unintended

pregnancy and STIs. Feedback included stage of readiness to use common contraceptive methods (e.g., oral contraceptive pills, abstinence, etc.), and selected pro/con statements for specific contraceptive methods. The printout also contained a list of participant- identified contraceptive use problems. Counselors offered and provided a demonstration of proper condom use, unless girls declined (seeking permission is consistent with MI). A detailed assessment of pregnancy intentions was obtained to determine how strongly a girl wanted to avoid a pregnancy. This information was used to highlight discrepancies between a girl's pregnancy plans and contraceptive and sexual behaviors. Alternatively, a girl may not have been trying to become pregnant but may have stated that she would be "happy" if she became pregnant. In this case counselors discussed what it means to become pregnant, helped the participant decide what she would need to do to have a healthy pregnancy (e.g., avoid drugs/alcohol) and encouraged the initiation of folic acid as well as highly effective contraception until she is sure about her pregnancy plans and preparedness to have a child. If a participant was unsure or did not want to start a contraceptive method, then she was invited to participate in counseling on the risks that can be involved in teen pregnancy.

Session 2 began with a review of the previous feedback and a check-in of the girl's current intentions for behavior change. The printout concluded with an assessment of the participant's level of motivation and confidence in her ability to a) prevent pregnancy, b) use the methods of contraception she said she plans to use in the future, and c) avoid STIs. The session culminated in the counselor and participant collaborating on a SAFE (**S**ex/contraception, **A**bstinence back- up, **F**eedback and **E**ducation) plan, which was printed out for the participant. SAFE plans included a specific contraceptive plan, reasons for the plan, potential barriers to completing the plan and some possible solutions (including social supports). *Counselors introduced negotiation skills with girls to enhance confidence in using techniques with partners to reduce pregnancy and STIs (use of condom, etc.)*. Guided by the feedback printout, her 90 day substance history, and her pregnancy risk assessment, CAMI sessions focused on: 1) motivating girls to initiate and continue highly effective contraceptive methods or to be abstinent; 2) pregnancy prevention (or plan for a pregnancy) and reducing STIs that could compromise fertility; 3) continuing highly effective contraceptive behaviors for girls who have already adopted safe sexual behaviors; and 4) initiating a Title X clinic appointment (or other medical follow up) for girls interested in contraceptive method (*this includes identifying and addressing barriers to keeping the appointment)*. Challenges such as cost, homelessness, lack of resources due to developmental age, substance use and issues related to education, crime and mental health were also discussed throughout the sessions as relevant.

After completion of CAMI, the participant completed a Satisfaction Questionnaire. Prior to leaving the session, the participant was offered educational pamphlets and a referral to see a family planning provider in the community (Title X). Which pamphlets were taken and whether a referral was accepted to the family planning provider were recorded. The Counselor then completed the Stage of Change Scale assessing the participant's readiness to use highly effective contraceptives, and a Counselor questionnaire on how the intervention went (e.g., "Participant thought it was easy to talk to me").

Didactic Educational Counseling (DEC). DEC was designed to provide information on contraception and STI prevention. The content of the information is similar to that often provided in family planning clinics and in primary care settings. It was delivered in two 60-

minute didactic sessions at enrollment and during 3- month follow-up. The content of this information-based, advice-oriented control was modeled after Title X Family Planning Counseling Guidelines.[13] The guidelines state that counselors should provide ample information regarding the risks, benefits, contraindications, and effective use of any method of contraception.

The DEC curriculum contained 2 modules of didactic information on 1) contraception, STIs and their prevention; abstinence as a contraceptive and STI prevention method; and 2) a review of previous materials at 3-month follow-up. Counselors were taught to invite DEC participants to ask questions about the didactic materials as they reviewed them, but to avoid an MI intervention approach. In session 1, the counselors reviewed all available contraceptive methods with an emphasis on contraceptive methods that are appropriate for this population (e.g., pills, Depo-Provera, condoms, etc.). The session included a review of available contraceptive methods and included a discussion of effectiveness across methods. The menstrual cycle was reviewed including ovulation, fertilization, implantation and where in this cycle each method works. Visual aids (posters, pamphlets) were used to illustrate methods. Advantages, disadvantages and access issues were reviewed (where the method can be obtained, cost, insurance coverage, and duration of action). In session 2, information about STIs and their prevention was covered. Discussion included signs and symptoms of each infection, cause, treatment, and prevention. Finally, abstinence was discussed as a contraceptive and STI prevention method. A Satisfaction Questionnaire was completed. The session closed with the counselor giving the participants pamphlets on contraception and STI prevention. After the DEC participant left, the counselor completed the same materials as they would complete after a CAMI session.

Participants in the DEC group did not receive any personalized feedback and did not create a collaborative SAFE plan. Although there is overlap in some information presented in the two groups, the style and spirit of CAMI is different from DEC in that CAMI is based on Readiness and MI; whereas DEC is more didactic, and question and answer based. CAMI utilizes open-ended questions, provides advice for change (with permission), and utilizes reflective listening and summaries to elicit a girl's desire, ability, reasons, need and commitment for change.[14] These are integral to MI as used in CAMI, and are not part of the DEC intervention.

Ending Every CAMI & DEC Session. Counselors offered both CAMI and DEC participants a list of community-based locations at which contraceptive services and STI screening can be accessed inexpensively or for free. The counselor recommended that the participant visit her primary care provider or one of the sites on the list for contraceptive supplies, annual pelvic examinations and regular STI screening. Each participant was offered a bag of 2 dozen condoms.

Assessment Procedures and Measurement.

Research staff administered questionnaires using computers. Measures included primary and secondary outcomes (both behavioral and biological), background measures, process measures, and post-intervention assessment. Methods used in this trial to minimize self-report bias included: (1) informing participants that the researchers administering interviews are from the University of Rhode Island; (2) reassuring participants that the information provided is

confidential; (3) using multiple measures of sexual behaviors and contraceptive use through the various questionnaires and TLFB. Biologic samples were utilized and help confirm self-report. As part of participating, girls were asked to provide a release to contact health providers (in order to confirm self-reports).

At baseline, the research staff member facilitating the computer assessment was the same person implementing the intervention but did not know which condition the participant was in until after the assessment. By keeping the research interviewer blind to treatment condition, introduction of bias was decreased. A different staffer, blind to the intervention group of the participant, implemented subsequent assessments. Hence the person collecting the data was "blind" to the intervention assignment. The person who collected calendar-assisted information did not know the participant's group assignment. The standardized and quantitative nature of the questionnaire also decreased the possibility of interviewer bias.

Design Considerations.

A no-treatment-control comparison was considered, but the current study is a more stringent test of hypotheses. Extending the assessment period to 12 months was considered but it is first important to illustrate a treatment effect (future studies can focus on extending effects). Delaying teen pregnancy by 9 months produces significant health benefits to families and society.[15]

Selection.

Inclusion criteria. 1) *Age 14-21*; 2) Currently sexually active with males defined as having had coital sex and intending to have coital sex within the next 6 months; 3) Willing to comply with protocol, follow-up assessments, and provide at least one locator; and 4) Fluent in English.

Exclusion criteria. 1) Inability to give informed consent secondary to organic brain dysfunction, or active psychosis or otherwise not able to participate in the intervention or assessments (deaf, blind, or impaired communication skills that preclude participation in computerize assessment or counseling); 2) Girls who were not sexually active; or 3) Girls who were currently pregnant.

Sample size.

Sample size was determined using power analysis for hypothesis tests related to primary aims. Based on the power analysis, a total of 250 teens were to be recruited in order to retain a minimum sample size of about 200 (80% retention) at 9-mo follow-up (FU). Anticipated FU rates were 90%, 85% and 80% at 3-, 6- and 9-mo FU, respectively. These numbers are conservative and are based on comparable recruitment and FU rates as found in the principal investigator's lab. In probation alone, about 311 female teens per year were placed on probation and about 85% met screening criteria (see above). See Table 1 for the study's anticipated flow. Youth were recruited from venues on a first come.

Participant Flow:

Year	Baseline	3 Month Follow-Up	6 Month Follow-Up	9 Month Follow-up
1	47	28	10	0
2	72	64	60	48
3	72	63	60	53
4	59	62	60	54
5	0	8	22	45
Total	250	225	212	200

Primary Outcomes (assessed at baseline and follow-ups).

Initiation and Continuous Use of Highly Effective Contraceptives at 3, 6, and 9 Months. A participant switching from one highly effective contraceptive method to another was recorded as maintaining continuous contraceptive use at follow-up if she switched methods during times when the original method was still effective. Use of contraceptive methods was assessed through the TLFB (see below).

Incident STIs. At baseline participants were tested for *T. vaginalis, N. gonorrhoeae, and C. trachomatis* through self-obtained vaginal swabs. If a participant was diagnosed with an STI at baseline she was to be referred for treatment at a Title X clinic and retested at her next follow-up visit. Any positive test after a baseline negative test was documented as an incident infection. These STIs encompass the most common infections seen in sexually active girls and can result in adverse reproductive sequelae such as infertility, chronic pelvic pain, increased HIV risk and elevated risk of ectopic pregnancy. Other STIs (human papilloma virus, Herpes simplex virus and Syphilis) are not included as the incidence of primary disease in RI is low and diagnosis may require a physical exam or serology.

Secondary Outcomes (assessed at baseline and follow-ups).

Incident Pregnancy. An incident pregnancy was defined as having occurred if there is a baseline negative pregnancy test and a positive urine at follow-up (using a Beta-HCG test) or a self-reported pregnancy confirmed with a positive urine.

Risk for Unintended Pregnancy and STIs. Risk behaviors was determined through the TLFB (see below). No or low risk for an unintended pregnancy included either continuous use of a highly effective contraceptive method, abstinence, or use of a condom with a spermicide during every act of intercourse. No or low risk for STIs included abstinence or use of a condom with every act of intercourse and with every partner.

Timeline Followback (TLFB). Contraceptive, sexual and drug-related risk behaviors were measured via a calendar recall behavioral assessment for both interventions[16].

Predictive Measures (assessed at baseline and follow-ups).

TLFB was used to assess drug use. Homelessness Status, Incarceration Status, and Pregnancy Intentions/Plans[17] were assessed.

Sexual and Relationship Measures. Participants were queried regarding sexual orientation, attraction and experience, and sexual assertiveness[18]. The participant's perception of their primary partner's influence on condom use and birth control was assessed.

Background Information (assessed at baseline). a) Demographics, b) Obstetric and gynecologic history, c) Length of probation, d) Barriers to family planning services, e) Medical insurance, f) Primary care provider or clinic, g) Relationship violence (measured with 10 items adapted from the Conflict Tactics Scale[19]); h) Sexual victimization (measured with a 12-item modified version of the Sexual Victimization Scale[19]), i) Childhood sexual abuse (measured by 8 questions adapted from a measure developed by Wyatt).[20]

Process Measures (assessed at baseline and follow-ups).

Readiness Rulers. These were administered to identify participants' readiness to use each method of contraception before and after each counseling session and during follow-up[21-22].

Importance and Confidence Scales. Participants rated on a scale from 0 to 10 how important it is to use each method of contraception (0 = least important, 10 = most). Confidence in using each method is assessed in similar fashion (0 = least confident, 10 = most). The ratings of importance and confidence were used in the CAMI to elicit reasons for change and reasons to be confident in ability to change.[16]

Post-Intervention Assessments (assessed at the end of intervention).

Satisfaction Survey. CAMI and DEC participants completed this 18-item survey of closed and open-ended questions on acceptability of the computerized assessment and counseling. The CAMI participants' survey also contains questions about the perceived fit of the risk assessments for pregnancy and STIs and acceptability of the SAFE plan. All participants completed an abbreviated satisfaction survey at the 9-month follow-up to assess long term satisfaction with the intervention.

Data Analysis.

Sample Size Considerations. Based on the following calculation, we proposed baseline N = 250 subjects.

Specific Aim #1, increasing initiation of highly effective contraception. It is anticipated that CAMI intervention to have a moderate effect on contraceptive initiation rate, resulting in 20% starting a contraceptive method in the treatment group. **Follow-up N = 200 will provide 95% power with a 0.05 two-sided significance level.**

Specific Aim #2, continuation of highly effective contraceptives. Assuming an average within-subject correlation of 0.50, corresponding to a design effect of 2.5, approximately 125 subjects for each group at baseline will provide 80% power for this analysis. In other words, the proposed total sample size of 250 participants at baseline will be enough to achieve excellent

power after considering 20% attrition rate over 9 months (assume continuation increase of 9% for controls and 24% for the intervention group, based on CAMI pilot data).
The secondary outcome of documented pregnancy (Aim 2) will not be powered to detect between group differences. These data are exploratory in nature and inexpensive.

Specific Aim #3, decrease in unsafe sexual activity, the primary outcome is incident STIs. The following is assumed: Type I error of α=.05, an average within-subject correlation of 0.50 and 20% attrition rate. Using similar procedures as above, the proposed enrollment of 250 participants at baseline will achieve power of 80% to detect differences after considering 3 repeated measures (3, 6, 9 months). For the secondary outcome in Specific Aim #3, decrease in unsafe sexual activity, the following is assumed: Type I error of α=.05, an average within-subject correlation of 0.50 and 20% attrition rate. Using the similar procedure as above, the proposed enrollment of 250 participants at baseline will achieve power of 97% to detect assumed differences. The proposed sample size may provide greater power to detect interaction effects, robustness to violations of model assumptions, protection against multiple comparison error rates, and increase efficiency to detect weaker relationships between variables.

Descriptive Analysis. Initially, descriptive statistics were used to summarize the variables as well as detect outliers, data entry mistakes, and missing values. Effectiveness of the randomization procedures was assessed through comparison of the two treatment arms on all baseline measures. Comparisons of baseline characteristics used Student's t-test, and Chi-square test. Data analyses were performed using "Statistical Analysis Software" (SAS Institute, Inc, Cary, North Carolina). All significance tests will be two-tailed.

Primary Analyses. Following intention-to-treat principles, all participants who have been randomized to the two conditions will be included in the analyses. Differential attrition across treatment groups was not expected, but this unlikely occurrence was assessed.

Contraceptive Initiation (Aim #1). Analyses of contraceptive initiation included the percentage starting a highly effective method (DepoProvera or an IUD) and highly effective methods requiring regular non-coital use (contraceptive pills, vaginal rings, the patch etc). This intent-to-treat analysis used multiple logistic regression to determine if girls randomized to the CAMI condition were more likely to initiate a contraceptive method than girls randomized to the DEC condition. The background characteristics (age, gender, race) or baseline characteristics (e.g., pregnancy related variables, and contraceptive history) and some meaningful interaction terms will be incorporated in the initial full model. All the p values are calculated with two-sided significance level of 0.05. Odds ratios and their 95% confidence intervals will be calculated for any important explanatory variables.

Contraceptive Continuation (Aim #2). Testing interactions between treatment and time illuminated whether differences in contraceptive outcomes between treatment conditions became more or less pronounced over the 9 months of follow-up.

Incident STIs (Aim #3). All STIs tested through the study were evaluated. Generalized linear mixed model (GLMM) were used to test this hypothesis, and procedures similar to those outlined in Aim #2 were used.

Secondary Analyses (Aim #2 and Aim #3). The following were utilized 1) pregnancy incidents and 2) the TLFB to identify the percentage of at-risk-days that girls engage in unprotected sexual activity. GLMM was used to test this hypothesis, and procedures similar to those outlined in Aim #2 will be followed.

Predictors of contraceptive use. These included demographics of age, race/ethnicity and education as well as drug and alcohol use, recent and childhood victimization and pregnancy history. Measurement modeling was used to incorporate multiple measures, such as the self-reported primary outcomes and the incidence of pregnancy and STD in a latent factor that captures variance common to all measures[24].

Missing Data. Because the primary outcome variable, initiation of a contraceptive method, was to be observed for all participants, missing data posed minimal threat to the internal validity of the intervention in determining contraceptive initiation. In the event of item non-response occurring, multiple imputation was to be used to estimate adjusted treatment effects.[24] For multiple imputation, 10 data sets were to be generated using SAS Proc MI and the companion procedure PROC MIANALYZE was to estimate the logistic regression model corresponding to analyses for each of the individual aims. If there were differences in the outcomes as a function of missing data pattern, then missing data pattern was to be included as covariate in the analyses.

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