

Official Title: Contraceptive Awareness and Reproductive Education

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

The University of Rhode Island

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Study Overview

There are approximately 311 girls on probation in the state of Rhode Island, making up 17% of the adolescent probation population. Nationally, from 1985 to 2005, the proportion of female probationers has risen from 18% to 26%.¹ JJ-involved girls engage in sexually risky behaviors and tend to have higher rates of STIs than girls in the community² and higher rates of pregnancy.³ National standards identify STI testing and treatment and prenatal health care as essential for JJ-involved juveniles, yet many jurisdictions fail to provide these basics.^{4,5} This study addresses an important public health problem by evaluating the efficacy of an intervention to reduce STIs and unplanned pregnancies among adolescent female probationers, a highly underserved population in great need and at great risk for negative consequences from sexual behavior.

Study Objectives:

Primary 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 juvenile justice involved girls more than DEC. The **primary outcome** is initiation of a highly effective contraceptive method. This will be measured by documentation of having received a contraceptive injection, pills, patch or other device. Type of contraceptive and amount given will be recorded.
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 the timeline follow back (TLFB) calendars and confirmed with a review of medical records. 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 the TLFB.

Study Design:

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, will be administered at the 3-month follow-up visit following the assessment. Follow-up will occur at 3, 6, and 9 months following initial contact and will occur in the community or at a Probation office.

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 will be 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 discuss sexual and contraceptive history, pregnancy and STI risk level, and substance use over the past 90 days to identify potential 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 criminal justice issues were also discussed throughout the sessions as relevant. After completion of CAMI, the participant completed a Satisfaction Questionnaire and a Therapeutic Alliance 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 Therapeutic Alliance Questionnaire.

Didactic Educational Counseling (DEC)

The 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 the DHHS, Title X Family Planning Counseling Guidelines.⁶ 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. 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. DEC participants were provided pamphlets and did not choose pamphlets as the CAMI participants did. Although there is overlap in some information presented in the two groups, we believe 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 change⁷. 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 Measures.

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.

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, we decreased the introduction of bias. 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 TLFB information did not know the participant’s group assignment. The standardized and quantitative nature of the questionnaire will also decrease the possibility of interviewer bias.

Design Considerations. We considered a no-treatment-control comparison, but the current study is a more stringent test of our hypotheses. We also considered extending the assessment period to 12 months but felt that 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 society⁸.

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 include: 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) who were currently pregnant.

Sample size was determined using power analysis for hypothesis tests related to our primary aims. Based on the power analysis, we aimed to recruit a total of 250 teens in order to retain a minimum sample size of about 200 (80% retention) at 9-mo follow-up (FU). We anticipate FU rates of 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 in our studies of juvenile justice-involved adolescents. About 311 female teens per year are placed on probation and about 85% meet screening criteria (see above). See Table 1 for the study’s anticipated flow.

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 will be recorded as maintaining continuous contraceptive use at follow-up if she switches methods during times when the original method is still effective. Use of contraceptive methods will be assessed through the TLFB (see below).

Incident STIs: At baseline participants will be tested for *T. vaginalis*, *N. gonorrhoeae*, and *C. trachomatis* through self-obtained vaginal swabs. If a participant is diagnosed with an STI at baseline she will be referred for treatment at a Title X clinic and will be retested at her next follow-up visit. Any positive test after a baseline negative test will be 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 will be 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 will be determined through the TLFB (see below). No or low risk for an unintended pregnancy will include 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 include 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 will be measured via a calendar recall behavioral assessment for both interventions.⁹

Predictive Measures (assessed at baseline and follow-ups)

TLFB are used to assess drug use. Homelessness Status, Incarceration Status, and Pregnancy Intentions/Plans¹⁰ was assessed.

Sexual and Relationship Measures: Participants were queried regarding sexual orientation, attraction and experience, and sexual assertiveness¹¹. 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 Scale¹²); h) Sexual victimization (measured with a 12-item modified version of the Sexual Victimization Scale¹²), i) Childhood sexual abuse (measured by 8 questions adapted from a measure developed by Wyatt¹³).

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.¹⁴⁻¹⁵

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)

Working Alliance Inventory, Short Form–Participant Version (WAI-S): This is a 12-item self-report questionnaire of participant bond with counselor, and agreement on goals and tasks.¹⁷ We have adapted the measure to address differences in setting (counseling instead of therapy) and roles (counselor instead of therapist). Counselors completed a parallel version (WAI-C). The measure takes 4 minutes to complete.

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 will complete 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.

Regarding Specific Aim #1, increasing initiation of highly effective contraception. We anticipated the 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, our 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). For the secondary outcome of documented pregnancy (Aim 2) we 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. We assumed a type I error of $\alpha = .05$, 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, and 9 months). For the secondary outcome in Specific Aim #3, decrease in unsafe sexual activity, we assume a type I error of $\alpha=.05$, 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. Our 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. We will assess the effectiveness of the randomization procedures through comparison of the two treatment arms on all baseline measures. Comparisons of baseline characteristics will use Student's t-test, nonparametric test and Chi-square test. Data analyses will be performed using SAS 9.1.3 (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. We do not expect differential attrition across treatment groups, but we will assess for this unlikely occurrence.

Contraceptive Initiation (Aim #1). Analyses of contraceptive initiation will include 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 will use multiple logistic regression to determine if girls randomized to the CAMI condition are 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 will inform us whether differences in contraceptive outcomes between treatment conditions become more or less pronounced over the 9 months of follow-up. The area under the Receiver Operating Characteristic curve (C- index) will be calculated to evaluate the concordance between predicted probabilities and observed results.

Incident STIs (Aim #3). We will evaluate all STIs tested through the study. Generalized linear mixed model (GLMM) will be used to test this hypothesis, and we will use procedures similar to those outlined in Aim #2.

Secondary Analyses (Aim #2 and Aim #3): We will utilize 1) pregnancy incidents and 2) the TLFB to identify the percentage of at-risk-days that girls engage in unprotected sexual activity. GLMM will be used to test this hypothesis, and we will follow similar procedures outlined in Aim #2.

Predictors of contraceptive use: These will include demographics of age, race/ethnicity and education as well as drug and alcohol use, recent and childhood victimization and pregnancy history. We will use measurement modeling 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.¹⁸

Missing Data. Because the primary outcome variable, initiation of a contraceptive method, will be observed for all participants, missing data poses minimal threat to the internal validity of the intervention in determining contraceptive initiation. If item non-response occurs, multiple imputation will be used to estimate adjusted treatment effects.¹⁸ If multiple imputation is required we will generate 10 data sets using SAS Proc MI and use the companion procedure PROC MIANALYZE to estimate the logistic regression model corresponding to analyses for each of the individual aims. If there are differences in the outcomes as a function of missing data pattern, then missing data pattern will be included as covariate in the analyses.

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