

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

**Patient Centered Support for Contraceptive Decision-Making:
A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool**

Principal Investigator: Christine Dehlendorf, MD MAS

Contact Person: Judith Fitzpatrick

CHR Continuing Approval Reference Number: 14-12865

Expiration Date: 9/6/2017

I.	General Study Information	2
A.	Background	2
B.	Study Aims	3
II.	Study Design.....	4
III.	Study Procedures	4
A.	Pre-Intervention Phase Procedures	4
1.	Pre-intervention Audio Recordings.....	4
2.	Randomization	5
B.	Intervention Phase Procedures.....	5
1.	Patient Follow-Up Survey.....	7
2.	Disenrollment.....	8
3.	Blinding	8
C.	Post-Intervention Phase Procedures	9
1.	Provider and Clinic Staff Interviews	9
IV.	Eligibility	10
A.	Inclusion criteria for patients.....	10
Exclusion criteria for patients	10	
B.	Inclusion criteria for providers.....	10
C.	Inclusion criteria for clinic staff members	10
V.	Participant Recruitment.....	11
A.	Planned Parenthood of Northern California on Valencia St.	11
B.	San Francisco City Clinic, Department of Public Health.....	11

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

- C. City College of San Francisco Student Health Center 11
- D. The Women’s Clinic at San Francisco General Hospital (5M) 12
- E. Staff Recruitment (all clinics) 12
- VI. Participant Payments 12
- VII. Data Collection and Analysis 13
 - A. Outcomes of Interest 13
 - B. Sample Size: 16
 - C. Methods of Analysis 17
 - D. Data Management 20

I. General Study Information

A. Background

Approximately 50% of pregnancies in the United States are unintended. One factor contributing to this statistic is the non-use of effective contraceptive methods, including the fact that many women discontinue their chosen method shortly after initiating it. The family planning visit presents an opportunity to assist women to achieve their reproductive goals through providing adequate information and helping women to choose the best method for them. Decision support tools are ideally suited to this setting, as they have been found to help patients make value-concordant decision in preference-sensitive decisions such as the choice of a contraceptive method.

The study team has developed a tablet-computer-based tool that is designed to transform the process of contraceptive counseling between a patient and her family planning provider in multiple ways. As our goal is not to replace the process of counseling with the provider, but rather to facilitate it, we have designed our tool with the intent of having a beneficial impact on provider-patient communication through promoting shared decision making.

Our tool, called “MyBirthControl,” is a tablet-based tool that women will use immediately prior to their visit. Through facilitating shared decision making between the woman and her provider, this tool will facilitate women being able to choose a contraceptive method that is the best fit for her values and preferences. and that therefore she can use consistently and correctly, decreasing her risk for an unplanned pregnancy.

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

MyBirthControl is interactive and will be available in English and Spanish. The design for the tool consists of 5 modules:

- 1) An educational session reviewing the five areas determined to be most relevant to the choice of a contraceptive method based on our formative work and consultation with stakeholders and a review of the literature: effectiveness, side effects, return to fertility, and mode and frequency of administration.
- 2) An interactive component allowing women to indicate their preferences for the method characteristics described in #1 (the values clarification exercise)
- 3) A checklist assessing women's medical eligibility for different contraceptive methods
- 4) An interactive "method chooser" screen that highlights specific methods most appropriate for each woman based on responses to items 2 and 3 above, and allows the woman to navigate through information about the different methods. On this screen, she can compare the methods that are appropriate for her based on her answers to different questions, allowing her to weigh the relative importance of, for example, side effects of a method and its efficacy on her method choice.
- 5) A screen that allows her to indicate what questions she has, with example questions provided.
- 6) A final screen that allows women to print out their method preferences (#2), relevant medical history (#3), questions they wish to ask their health care provider (#5), and the methods that they are most interested in. This print-out is designed to be shared with the medical provider.

B. Study Aims

Our aims are as follows:

Aim 1: To determine the impact of the implementation of a contraceptive decision support tool on women's contraceptive continuation and their experience of receiving contraceptive counseling, including decisional conflict, compared to women receiving usual care.

Aim 2: To qualitatively compare the contraceptive counseling provided to patients who have used the decision support tool prior to their visit and those who have not use the tool.

Aim 3: To assess the experience of providers and health care delivery systems with use of the intervention in the clinical setting.

This study is funded by the Patient-Centered Outcomes Research Institute contract number CE-1304-6874. Study activities will follow Dr. Dehlendorf's Standard Operating Procedures for all procedures not detailed in this study protocol.

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

II. Study Design

This is a cluster randomized controlled trial to investigate the effect of our contraceptive decision support tool on women's contraceptive continuation, as well as on their experience of contraceptive counseling, measured both quantitatively and qualitatively. In addition, we will collect quantitative and qualitative data to determine the impact of the implementation of this tool on the experience of providers and the clinics in which they work. Data collection will occur in three stages: 1) pre-intervention phase, 2) intervention phase, including follow-up of patients for seven months, and 3) post-intervention phase. For phase 1, immediately before implementing the contraceptive decision support tool, we will collect audio recordings of contraceptive counseling visits. For phase 2, we will randomize at the provider level to usual care or use of the intervention. For phase 3, we will conduct audio recordings of contraceptive counseling visits with providers in the intervention arm, as well as performing interviews of intervention providers and focus groups with clinic staff. We will use best practices for the conduct and reporting of this type of trial as detailed in the CONSORT guidelines.

III. Study Procedures

As described, this study has three main phases, outlined below. All study procedures will be conducted by UCSF study staff or UCSF study volunteers.

A. Pre-Intervention Phase Procedures

In the pre-intervention visit recording phase, we will recruit patients at the study clinics prior to implementing the intervention. Subsequently, providers will be randomized into the control or intervention arm of the study.

1. Pre-Intervention Audio Recordings

The procedure for provider participants is as follows:

- The study will be discussed at staff meetings or individually, as determined by each clinic.
- Each potential participant will then be contacted individually to have their questions answered and determine if they are willing to consent to participate. Study staff will obtain written consent for the pre-study visit recording phase and the study intervention phase at this time.
- After enrolling in the study, each provider will conduct 2-3 family planning visits in the usual fashion as are performed at the clinic with patients participating in this phase of the study.
- During these visits, the conversation between patient and provider will be recorded on a secure voice recorder.
- The recordings from these visits will be transcribed on a computer by a HIPAA-compliant transcription service.

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

- After completing three visits, each provider will complete a survey about their demographic characteristics and the Maslach Burnout Inventory.

The procedure for patient participants is as follows:

- After being screened and consented by study staff, each patient will complete a short demographic survey (**Note:** This survey was not added to study procedures until 11/4/15, when a minor modification detailing it was approved) and have a family planning visit in the usual fashion as is performed at the clinic with providers participating in the study. As described above, the conversation between patient and provider will be recorded on a secure voice recorder during these visits, and the visits will be transcribed.

2. Randomization

After the pre-intervention phase and before the intervention phase, the provider participants will be randomized into intervention and control arms, stratified by clinic. Providers will be randomized using a random number table, clustered by each clinic. Dr. Vittinghoff will create a random number table using Stata 13's "ralloc" randomization module and blinded study IDs provided by study staff. The decision support tool intervention will then be introduced in a short orientation to the providers randomized to the intervention arm.

B. Intervention Phase Procedures

Study staff role: UCSF Research Assistants will track all recruitment activity using the clinic-specific Recruitment Tracking Log daily. Weekly totals will be tallied each Friday afternoon. At each recruitment shift in each clinic, there should be one UCSF Research Assistant (RA) who conducts eligibility and consent processes, and, if possible, one volunteer or Patient Stakeholder Representative who assists the RA with completing tracking logs, the time study, and managing iPads and other study equipment. Time study data will be collected in this phase the same as in the pre-intervention phase: patient arrival time, tool start and end time (if applicable), visit start time with clinician, and visit end time.

The procedure for provider participants is as follows:

- Each provider will conduct up to 45 family planning visits (not including visits during which the patient participant was given a pregnancy diagnosis, which is a post-randomization exclusion criterion) in the clinic with patients participating in this phase of the study.
- Providers who complete 40 visits before the end of the study will be approached and further recruitment for them is feasible, we will approach them to be re-consented to complete a maximum total of 45 visits per provider, in accordance with our IRB approval.
- After completing study visits for the intervention phase, all providers will complete another short survey via REDCap, consisting of the Maslach Burnout Inventory.

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

- After completing all visits and the second survey, providers in the control arm have completed their participation in the study while providers in the intervention arm move to the post-intervention phase.

In the intervention phase, we will recruit patients at the study clinics. The procedure for patient participants is as follows:

- After being screened and consented by study staff, each patient will complete a pre-visit survey regarding their contraceptive knowledge and preferences and provide her preferred and back-up contact information to the study staff and preferred method of contact for follow-up surveys.
- **Some patient participants may be randomized** to whether they see a control or intervention arm provider, if they are at a clinic that does not make appointments with specific providers and there are providers in both arms that are available to have an appointment with that provider. Both City Clinic and Planned Parenthood Valencia do not assign patients to a specific provider in advance of the start of their visit. Therefore, at these clinics, sometimes it will not be clear whether or not a participant should use the tool or not before her visit. At these two clinics, the RA who is recruiting will first see if it is obvious which study arm the patient should be in based on which providers are currently available to see family planning patients. In some cases, only one study provider will be working at a time, or all the study providers who are working will be in the same arm, so it will be clear which arm the patient should be in. At other times, multiple providers may be working but there may be only one who speaks the patient's language or who is not about to start a long procedure, so it is clear which arm the patient will be in. In the remainder of cases, in which there is at least one provider from each study arm (tool and control) available to see patients at the same time, the RA will use a program written in R, the statistical software program, to randomly assign the patient to see either a tool or control provider. The randomization module was written by Dr. Eric Vittinghoff, our study statistician, and is installed on the study laptops and RA iPhones. An RA simply has to open R and type in the command "randomize" along with the ratio of tool to control arm providers who are currently available (i.e., "Randomize(1,1)") and the program will produce an assignment. The RA will then do her best to work with clinic flow to ensure that the patient sees a provider in the appropriate arm. As described in the analysis section, if the patient ultimately sees a provider in the non-randomized arm, she will be analyzed in the assigned arm using intention to treat principles.
- **Randomization will be considered the point of enrollment in the study.** For patient participants that are at a clinic that makes appointments with specific providers, this will be decided by the clinic schedule and arm assignment will be recorded upon completion of the pre-visit survey. For patient participants that are at City Clinic and Planned Parenthood, the point of enrollment in the study will be when the randomization procedure described in the previous paragraph has been completed. Prior to being randomized, if an eligible patient participant does not wish to continue with study procedures, they will be considered as a "decline to participate." If they do not wish to continue with study procedures after the point of randomization, they will be considered "dis-enrolled."

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

- If the patient's family planning appointment/randomization assignment is with a provider in the intervention arm, she will interact with the MyBirthControl contraceptive decision support tool while in the waiting room. The RA or volunteer will note the unique tool ID number that is generated on the start screen of the tool and log this in the recruitment tracking log so that back end tool data can be analyzed at a later date.
- In the intervention arm, the tool will generate a printout for each patient that contains information about their preferences for contraception, their reproductive intentions, their medical history, and questions that they have for their provider. This paper will then be shared with the provider. The printout will be destroyed by study staff immediately after the clinic encounter or taken home if the patient requests it, so that it does not become a part of the patient's medical record (in order to limit the possibility of contamination between arms).
- Patients seeing a provider randomized to the control arm will then have a family planning visit in the usual fashion, as performed by that provider.
- After the visit, each patient will complete a post-visit survey assessing their demographics, their contraceptive methods choice and their opinion of the counseling they received. If the patient must leave the clinic without completing her post-visit survey due to time constraints (and not because she wishes to withdraw from the study), study personnel will attempt to contact the patient using the contact information given at the time of the visit and have them complete the post-visit survey by phone or email. If the patient does not complete the post-visit survey within 48 hours of their initial visit, study personnel will continue to attempt to have them complete the post 48-hours version of the post-survey (in which the time-sensitive questions have been omitted) up to one month after the initial visit.
- Study staff will provide each patient with a flyer summarizing the timing of follow-up and with contact information for study staff in case participant changes her contact information or wishes to dis-enroll.

1. Patient Follow-Up Survey

Each patient will be contacted by whatever method they prefer (phone, mail, SMS, email) at four and seven months after the visit to complete a follow-up survey to assess whether they have continued their contraceptive method. The survey can be completed either over the phone with an RA or on the patient's own time online using REDCap.

- Patient contact information and enrollment dates will be entered into REDCap, where follow-up contact due dates will be calculated. RAs and volunteers will conduct follow-up attempts via the patient's preferred method, logging each attempt and its outcome in REDCap.
- In order to accurately assess whether Depo users got their next shot on time, 4 month follow up calls will begin at 112 days (16 weeks) and 7 month follow up calls will begin at 217 days (31 weeks).
- The secure UCSF email address birthcontrolstudy@ucsf.edu has been created and added to each RA's email account to facilitate participant follow-up by multiple people.

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

- Google Voice will be used for text and phone follow-up contact attempts. Contact information will be deleted from the program monthly.
- Contact attempts for the 4- and 7-month follow-up surveys will be declared unsuccessful after 4 weeks, but participants with unsuccessful contact at 4 months will still have contact attempts made at 7 months.
- Gift cards for completed surveys will be mailed, or can be picked up at the research offices at San Francisco General Hospital if the patient prefers. For more detail on participant reimbursements, see Section V.

2. Patient Disenrollment Procedure

Patients who no longer wish to participate will be withdrawn by the following protocol.

Paperwork

1. *If a participant disenrolls at baseline:* move any study participant consents and/or HIPAA forms) to the folder labeled “withdrawn patients,” stratified by clinic. Shred any contact information forms. Mark on any remaining paperwork the step that the participant was at when they disenrolled, e.g. Mark on consent that the participant disenrolled before completing the HIPAA form. *If a participant disenrolls at any point after baseline* (e.g. at 4 month follow-up), their consent and HIPAA forms should remain in the folder with the rest of the remaining enrolled participants. Shred contact information forms. The following procedure for electronic records should be followed for all participants regardless of when they disenroll from the study.

Electronic records

1. Mark “Yes” for “Dis-enrolled?” and complete reason for disenrollment in tracking sheet.
2. Mark participant as “dis-enrolled” in backend survey of REDCap.
3. Remove follow up dates from the calendar in REDCap.
4. Delete contact information if it was already entered in REDCap, including participant’s first name.

3. Blinding

Blinding of participants and study personnel at baseline was not feasible due to the nature of the intervention. At follow-up, study personnel conducting surveys by phone were not informed of study arm. Consent forms intentionally do not disclose the specific outcomes of interest (i.e., contraceptive continuation), so as not to influence participant behavior. Additionally, participants will not be aware of their arm assignment until after they have been consented. Study staff will be blinded during quantitative data analysis of provider and patient participant data and time study data. However, blinding will not be feasible during qualitative analysis of visits as the presence or absence of the

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

handouts that arise from the tool may be apparent during the discussion; we will note this limitation in interpretation of our results.

C. Post-Intervention Phase Procedures

In the post-intervention phase, we will recruit patients scheduled to see providers participating in the intervention arm at the study clinics. The procedure for patient participants is as follows:

- After being screened and consented by study staff, each patient will complete a brief demographic survey (**Note:** This survey was not added to study procedures until 11/4/15, when a minor modification detailing it was approved) and interact with the contraceptive decision support tool while in the waiting room.
- Patients will then have a family planning visit
- During these visits, the conversation between patient and provider will be recorded on a secure voice recorder.
- The recordings from these visits will be transcribed on a computer by a HIPAA-compliant transcription service.

The procedure for provider participants is as follows:

- Providers in the intervention arm only will complete a new consent form for their participation in this phase of visit recordings and interviews.
- Immediately after completing the intervention phase, providers in the intervention arm will conduct 2-3 family planning visits with patients participating in this phase of the study.
- During these visits, the conversation between patient and provider will be recorded on a secure voice recorder.
- The recordings from these visits will be transcribed on a computer by a HIPAA-compliant transcription service.

1. Provider and Clinic Staff Interviews

Provider interviews will take place at the study clinics in a private location, at a time of the participant's choosing. Only providers participating in the intervention arm will be interviewed regarding their experiences. These semi-structured interviews will provide additional information about the implementation of the intervention, including providers' perceptions of the influence of the tool on their counseling and how they felt it influenced patients' experiences. Clinic staff—including nurses, medical assistants and administrative staff—at each clinic will be consented to participate in focus groups and will then complete a brief demographic survey. In the focus group, the clinic staff will provide information about the perception of the intervention on clinic operations and their experiences

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

interacting with patients and providers. Audio from these interviews will be recorded on a secure voice recorder and transcribed by a HIPAA-compliant transcription service.

IV. Eligibility

Eligibility checking procedures are described under “Recruitment.” Inclusion and exclusion criteria are the same at all study sites.

A. Inclusion criteria for patients will be that they are women of reproductive age (ages 15-45), wish to discuss starting or changing a contraceptive method during their visit, speak, read, and understand English or Spanish, and have a history of sexual activity with men.

Exclusion criteria for patients will be that they previously enrolled in the study, they previously used the decision support tool at the Women's Community Clinic in San Francisco, they are unable to get pregnant, their appointment reason is for insertion of an IUD or contraceptive implant, they are currently pregnant, and they desire pregnancy currently or in the next seven months. The last criterion is designed to ensure we will have limited numbers of women that will discontinue their contraceptive methods during the study due to planning a pregnancy. Post-enrollment exclusion criteria, to be determined by the first question on the post-visit survey, include finding out you are pregnant at the clinic visit and having enrolled in the study more than once.

B. Inclusion criteria for providers will be providing family planning counseling in one of the participating clinics and planning to remain in this job role for at least six months. This will include MDs, DOs, nurse practitioners, physician assistants, and unlicensed counselors. Provider and clinic staff eligibility will be determined in staff meetings or individually with the PI and study coordinator, as determined by each clinic.

C. Inclusion criteria for clinic staff members will be working at one of the clinics in a job that includes patient contact, but does not solely consist of family planning counseling at the time of the implementation of the intervention.

Note: As of the CHR minor modification submitted on 10/15/15 and approved on 10/16/15 we changed the eligibility criterion from “working at one of the clinics in a job with patient contact, but not directly providing contraceptive counseling” to “working at one of the clinics in a job that includes patient contact, but does not solely consist of family planning counseling.” This was changed before our first focus group was conducted and was done because the clinic staff at one of our study sites, Planned Parenthood of Northern California on Valencia St., who would be able to contribute to the focus group all have provide some degree of family planning counseling at that site.

V. Participant Recruitment

Recruitment procedures will be tailored to meet the needs of each individual study site's clinic flow and procedures, after discussion with clinic managers and staff.

A. Planned Parenthood of Northern California on Valencia St.

At the request of the clinic, front desk staff or study staff will provide opt-out handouts to potential participants that they decide are potentially eligible based on visit type. At the request of the clinic, we will not recruit patients whose visit reason is abortion care or colposcopy. Study staff (the RA) will check the clinic daily schedule and approach potentially eligible patients to determine their interest in the study and provide them with the eligibility checklist or review the checklist with them privately. Patients who complete the eligibility checklist independently and indicate that they are not interested in participating will not be screened further. Interested patients who complete the eligibility checklist independently will accompany an RA to a private area to confirm whether or not she is eligible based on the written checklist, and to discuss any questions she has about the study. If the patient is eligible and still wishes to participate, the RA will complete the informed consent process and enroll her in the study. **Note:** As 4/2/15, we transitioned from having patients complete eligibility checklist handouts to having the RA assess for eligibility in a private area as done at other sites with the permission of Planned Parenthood.

B. San Francisco City Clinic, Department of Public Health

Study staff will call potentially eligible patients from the waiting room into a private area to determine if they are interested in hearing more about the study. Potentially eligible patients will be determined by looking at the clinic daily schedule. Recruitment will take place primarily during clinic hours that offer family planning – not during HIV clinic, at clinic request. If the patient is interested after hearing a short description of the study, study staff will assess her eligibility using either a written or verbal eligibility checklist. The RA will then bring the patient to a health education room to confirm her eligibility based on either the written or verbal checklist, and to answer questions about the study. If the patient is eligible and still wishes to participate, the RA will complete the informed consent process and enroll her in the study.

C. City College of San Francisco Student Health Center

Potential patient participants will be identified by RAs by looking at the clinic's daily schedule. If a patient's visit reason does not clearly show she is ineligible (i.e., because of age or existing pregnancy), our research staff will approach the patient to discuss the study and assess eligibility. Staff will first determine if she is interested in hearing about a study about birth control. If the patient is interested after hearing a short description of the study, study staff will assess her eligibility using either a written

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

or verbal eligibility checklist. Study staff will review her responses to the eligibility checklist and determine eligibility for the study. If additional clarification is needed regarding eligibility, the RA will then take the patient to a private area of the clinic to assess eligibility verbally. If the patient is eligible and still wishes to participate, the RA will complete the informed consent process and enroll her in the study.

D. The Women's Clinic at San Francisco General Hospital (5M)

Potential patient participants will be identified by RAs by looking at the clinic's daily schedule. If a patient's visit reason does not clearly show she is ineligible (i.e., because of age or existing pregnancy), our research staff will approach the patient to discuss the study and assess eligibility. Staff will first determine if she is interested in hearing about a study about birth control. If the patient is interested after hearing a short description of the study, study staff will assess her eligibility using either a written or verbal eligibility checklist. Study staff will review her responses to the eligibility checklist and determine eligibility for the study. If additional clarification is needed regarding eligibility, the RA will then take the patient to a private area of the clinic to assess eligibility verbally. If the patient is eligible and still wishes to participate, the RA will complete the informed consent process and enroll her in the study.

E. Staff Recruitment (all clinics)

Recruiting of provider participants and clinic staff will consist of group meetings in which the intervention and study procedures are explained and questions are answered by study staff. Study staff will attend clinic staff meetings as organized with each clinic's manager. Following these informational sessions, we will meet individually with staff to answer any additional questions and to provide all information necessary for informed consent by interested participants. Written informed consent will be obtained.

VI. Participant Payments

Patient participants in the intervention phase will receive a \$25 gift card when they enroll and complete the pre- and post-visit surveys. These participants will also be mailed a \$25 gift card for each completed 4- and 7-month follow-up survey for a maximum total payment of \$75.

Patient participants in the pre- and post-intervention audio recording-only phases will receive a \$25 gift card when they enroll and complete the audio-recorded family planning visit for a maximum total payment of \$25.

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

Provider participants will receive a \$125 Visa prepaid debit card when they enroll in the study and complete the baseline provider survey and baseline audiorecordings and \$125 when they complete the intervention phase for a total of \$250. Providers randomized to the intervention arm will receive an additional \$100 after completing the post-intervention interview and audio recordings for a total payment of \$350. Payment will be either provided directly to the providers on a prepaid debit card or paid to the clinic as determined in collaboration with each clinic and their guidelines.

Note: provider participants that see a high volume of family planning patients will be approached to be re-consented in order to exceed 40 visits with patient participants (up to 45 visits). If they re-consent they will receive an additional \$125 to recognize the additional time spent by these providers conducting visits as part of our study. For control providers who are re-consented to exceed 40 visits, this would result in a maximum total payment of \$375 (\$125 when they enroll + \$125 when they re-consent to exceeding 40 visits + \$125 when they complete the intervention phase). For intervention providers who are re-consented to exceed 40 visits, this would result in a maximum total payment of \$475 (\$125 when they enroll + \$125 when they re-consent to exceeding 40 visits + \$125 when they complete the intervention phase + \$100 when they complete the post-intervention procedures).

Clinic staff participants will receive a \$50 prepaid debit card when they enroll and complete the focus group discussion for a maximum total payment of \$50. Clinic staff will also receive refreshments during the focus group discussion.

VII. Data Collection and Analysis

The outcomes of interest for this study have been divided into three specific aims, which dictate what type of data is collected and how it is analyzed.

A. Outcomes of Interest

Specific Aim 1: The primary outcome is a binary indicator of contraceptive continuation at 7 months and a secondary outcome is a binary indicator of contraceptive continuation at 4 months. For ambiguous cases for these outcomes, we used a blinded adjudication process and applied a standardized list of rules and assigned outcomes throughout the process of data collection. Potential outcomes for individuals are as follows: continuous users of chosen method, non-continuous users of chosen method, and missing but included and imputed.

For all variables, the analysis will use multiple imputation to deal validly with the missing values. Of note, specific variables were not collected from participants we collected data from more than 48 hours after their visit. Those variables will be analyzed in the same way as other missing outcomes.

- **Primary outcome:**

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

- Continuation of the chosen method seven months after her visit, without a gap of four consecutive weeks or more.
- **Secondary outcomes:**
 - Patient Contraceptive Counseling Satisfaction at post-visit survey
 - Factor analysis-validated survey created by the PI to assess patients' satisfaction with the contraceptive counseling experience.
 - Patient Chosen Contraceptive Method Satisfaction at the post-visit survey, and 4 and 7 months
 - 5-point Likert scale question regarding patient satisfaction with contraceptive method chosen.
 - Experience with Shared Decision-Making (measured at post-visit survey)
 - Patient report of having engaged in shared decision making with their provider and their experience with the decision making process, as well as qualitative coding of contraceptive counseling visits. The qualitative coding will focus on the presence or absence of shared patient-provider decision making and patient engagement in the decision making process, drawing on concepts from observational measures of shared decision making, as well as insights into the counseling process gained through our previous observational study.
 - Patient Decisional Conflict in Contraceptive Choice at the post-visit survey
 - Validated survey to assess patients' decisional conflict in medical decision making.
 - Patient Current Contraceptive Method Satisfaction at 4 and 7 months
 - 5-point Likert scale question regarding patient satisfaction with the contraceptive method they are currently using.
 - Patient Attitudes and Knowledge of Contraceptive Options and Features (post-visit survey)
 - Patient report of perceived knowledge of their options and questions derived from National Survey of Reproductive Contraceptive Knowledge and previous studies of contraceptive knowledge and attitudes.
 - London Measure of Unplanned Pregnancy at 4 and 7 months
 - Incidence of unplanned pregnancy among study participants.
 - Use of Any Moderately or Highly Effective Method of Contraception at 4 and 7 Months Follow-up
 - Whether patient is using an effective contraceptive method at 4 or 7 months follow-up survey.
 - Choice of a Highly Effective Method of Contraception at Baseline

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

- Whether patient chooses a highly effective contraceptive method at baseline visit.
- Use of a Highly Effective Method of Contraception at 4 and 7 Months Follow-up
 - Whether patient is using a highly effective contraceptive method at 7 month follow-up survey.
- Continuation of the chosen method 4 months after her visit.
 - Continuation of the chosen method four months after enrollment, without a gap of four consecutive weeks or more.

Specific Aim 2: Qualitative assessment of patient engagement and the presence of shared decision making between counseling provided before and after implementation of the decision support tool by providers randomized to the intervention group. As described above, the qualitative coding will focus on the presence or absence of shared patient-provider decision making and patient engagement in the decision making process, drawing on concepts from observational measures of shared decision making, as well as insights into the counseling process gained through our previous observational study.

Specific Aim 3:

- Qualitative assessment of providers' and staff members' experiences using interviews and focus groups
- Quantitative measures of consultation time and total clinic visit time
 - Total Clinic Visit Time
 - Total amount of time a patient spends in a clinic for a family planning visit, from check-in to check-out.
 - Time Spent with Contraceptive Counseling Provider
 - Total amount of time spent with the provider that is providing contraceptive counseling.
- Change in provider burnout, pre- and post-intervention, using the Maslach Burnout scale, measured prior to implementation of the intervention and at the end of the trial
 - Maslach Burnout Inventory:
 - Given to provider participants to measure emotional exhaustion, depersonalization, and personal accomplishment subscale scores.

Timing of Measures

Patient Outcomes

	Baseline clinic visit	4 months	7 months
Demographics	X		
Chosen method	X		

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

Continuation of chosen method		X	X
Use of non-barrier method		X	X
Decisional conflict	X		
Attitudes Knowledge of contraceptive options	X		
Satisfaction with contraceptive counseling	X	X	X
Incidence of unplanned pregnancy		X	X
Total clinic visit time	X		
Time spent with contraceptive counseling provider	X		
Satisfaction with chosen method	X	X	X
Satisfaction with current method		X	X

Provider Outcomes

	Pre-intervention	Post-intervention	Follow-up interview/recording (intervention arm only)
Demographics	X		
Provider burnout	X	X	
Provider/patient engagement in shared decision-making, measured qualitatively	X		X

B. Sample Size:

Specific Aim 1: We based our sample size calculation on our primary outcome, contraceptive continuation. Based on our previous studies in this population, we estimate that 50% of women in our control group will continue with their contraceptive method at seven months. Using this same data, we have calculated the intra-cluster correlation (ICC) of this response by provider and by clinic at ~0 and 0.021 respectively. Accounting for clustering and 20% loss to follow-up, as well as a inflation factor to account for differences in contraceptive initiation among those in clinics with IUDs and implants on-site as compared to those without these methods on site, a sample of 758 patients (approximately 32 patients for each of 24 providers) would provide 80% power in 2-sided tests with a type-I error rate of 5% to detect a 12 percentage point increase in continuation, to 62%. This difference in contraceptive continuation would be clinically meaningful and is consistent with effects reported in the contraceptive literature. Again using data from our previous study to estimate ICCs and baseline parameters, the sample will also provide 80% power to detect small-to-moderate but clinically significant differences in secondary outcomes as shown below.

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

Outcome	ICC		Design effect	Baseline SD/%	SES/ MDD
	Clinic	Provider			
Continuous measures					
Decision conflict scale	0.000	0.027	1.3	1.9	0.25
Satisfaction score	0.152	0.075	1.7	6.5	0.31
Dichotomous measures					
Choice of highly effective method	0.096	0.000	0.9	23%	10.9%
Shared decision making	0.006	0.024	1.3	46%	14.3%
Unintended pregnancy	0.005	0.001	1.0	5%	-4.5%
For continuous outcomes, the standard deviation (SD) and standardized effect size (SES) are reported; for binary outcomes, the baseline prevalence and absolute effect, both in percent.					

Specific Aim 2: We have estimated that audio recording 2-3 patient encounters at each time point (before and after implementation of the intervention) for each of the providers randomized to the intervention will allow us to achieve saturation and to meaningfully compare the pre- and post-intervention period.

Specific Aim 3: We will conduct focus groups at each of the four clinics involved in the study, and will conduct semi-structured interviews of each of the providers randomized to the intervention. For our quantitative measures, we estimate we will have the ability to detect a less than 0.5 SD difference in consultation time and total clinic visit time. For comparison of burnout among providers, our sample size will be 24, with 12 in each group, and therefore will have limited power. In order to optimize power, we will estimate treatment effects on the final score controlling for the baseline value. Using this measure, we anticipate having 80% power to detect a 0.5 to 1.1SD differences on each of the sub-scales of the Maslach Burnout Inventory, depending on with within-provider correlation of these responses.

C. Methods of Analysis

Patient and provider stakeholders will be involved in an iterative manner in all stages of planning of analyses and in data interpretation.

[IR-1] Data required for primary analyses will be inspected, cleaned, and locked before primary analysis is begun. Data checks will include examination of descriptive statistics for plausibility (e.g. plausible

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

participant age, scale values fall within scale options given), distribution, and missingness. Values with errors will be replaced as missing or, if a correction is verifiable through review of an individual's record, replaced with the correct value in the dataset in Stata 14. For the primary analyses, individual record reviews will be performed for any participants with circumstances in which the primary outcome of contraceptive continuation may be complicated. These include all participants who selected DMPA (The Shot or "Depo") as their main or bridge method choice; participants who stopped their method before their 4-month survey and restarted it again before their 7-month survey; participants who transitioned from use of their bridge method to use of their main method for birth control during the course of the study; participants who became pregnant during the course of the study, after their day of enrollment; participants who were not reached to complete a 4-month survey, but did complete a 7-month survey; and participants with partially complete survey records at 4 or 7 months [IR-4]. Participants who are negative for the primary outcome (i.e. discontinuous) at the time of their 4-month survey will be considered negative for the primary outcome at 7 months, regardless of whether they completed a 7-month survey or not. Baseline outcomes will also be examined for individuals who accidentally completed multiple surveys at baseline, with priority given to the first survey completed. Reliability of scales will be assessed using Cronbach's alpha, as well checks for predictive and discriminant validity. [IR-4]. Reliability of scales will be assessed using Cronbach's alpha, as well checks for predictive and discriminant validity.

Specific Aim 1:

We will assess imbalance by treatment assignment using cross-tabulations and comparisons of within group means and medians. Inference for balance on provider covariates will use chi-squared, Fisher's exact, t, and Wilcoxon tests as appropriate, while differences in patient characteristics will be assessed using mixed effects models with fixed effects for clinic and random effects for provider. [IR-3] Primary analyses of treatment effects will be intention-to-treat, according to treatment assignment, and without regard to use of the tool or seeing an intervention provider. Treatment effects will be estimated using mixed effects linear, logistic, proportional odds, and multinomial models, with fixed effects for clinic and random effects for provider.

Missing data. [MD-1] Missing data will have been minimized by active follow-up of participants. [MD-4] Missing data rates for primary and secondary outcomes as well as important covariates will be reported, in combination with summaries of the reasons for missingness, including dropout and pregnancy. [MD-2] All analyses will handle missing data using 20-fold multiple imputation of missing outcomes, based on iterative chained equations. [MD-3] Summary effect estimates, averaged over the 20 imputed datasets, as well as confidence intervals and p-values, will be calculated using standard methods that account for imputation error.

Sensitivity analyses. [MD-5] Because informative missingness would violate the covariate-dependent missing at random (CDMAR) assumption of the standard multiple imputation procedure, we will conduct

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

sensitivity analyses in which we multiply impute missing data under plausible informative missing data mechanisms – in particular, lower contraceptive continuation rates among participants with missing values of this outcome, in one or both arms. [DR-3] In addition, we will conduct sensitivity analyses controlling for any imbalanced pre-randomization characteristics (e.g., age and parity) that predict outcomes, using 5% changes in the coefficient for the intervention as the criterion for covariate inclusion in the adjusted model. To characterize the influence of individual providers, we will estimate best linear unbiased predictions of the provider effects, and also fit models with additional random provider-intervention interactions, to capture heterogeneity in the effects of the intervention. In all analyses, we will transform continuous outcomes as necessary to meet the normality assumption, model departures from linearity in the influence of continuous covariates, check for influential points, and identify potentially important interactions.

Heterogeneity of treatment effects. [HT-1] We will assess modification of the effect of assignment to the intervention by the following 5 pre-specified factors: age, race/ethnicity, language, parental education, and clinic. We will assess evidence for effect modification by adding the effect modifier and its interaction with the treatment assignment indicator to the primary analysis models specified above. To limit inflation of the type-I error rate, we will only estimate within-stratum treatment effects if the interaction is statistically significant at a Bonferroni-corrected $P = 0.01$, and will cautiously interpret findings. These analyses will use multiply imputed data and corresponding inference methods.

Specific Aim 2: For this aim, we will be assessing the effect of the intervention on counseling at the cluster (i.e., provider) level. We will use Dedoose software to analyze the audio recordings using modified grounded theory, with the coding performed by Dr. Dehlendorf, Reiley Reed, and Dr. Kimport, with input from patient stakeholder representatives. This coding will focus on the presence or absence of shared decision making and patient engagement in the decision making process. In conducting this coding, we will use concepts drawn from observational measures of shared decision making, including the OPTION scale and the Four Habits Coding Scheme, as well as insight into the counseling process gained through our previous observational study, to identify our initial thematic structure. We will perform iterative coding, with discussions between coders, the PI, and patient stakeholders to clarify concepts and resolve ambiguities. We will then, again in collaboration with stakeholders, qualitatively explore the extent to which the providers altered their behaviors following implementation of the intervention using memo writing, and ultimately compiling these into results.

Specific Aim 3: In order to determine the effect of the intervention on the experience of providing family planning care at the level of both the clinic and the provider, we will perform both qualitative and quantitative analyses. Quantitative analyses, including comparing consultation time and total clinic visit time for patients in the intervention and control group, will use similar methods to those described in Aim 1. We will also compare scores on each sub-scale of the Maslach Burnout Inventory (emotional exhaustion, depersonalization, and personal accomplishment), controlling for baseline values, between providers randomized to the intervention and those randomized to the control group in both bivariate

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

and multivariate analyses, again controlling for clustering by clinic. In addition, we will conduct a sensitivity analysis controlling for any imbalanced pre-randomization characteristics (e.g., age) that predict outcomes, using changes in the coefficient for the intervention as the criterion for covariate inclusion in the adjusted model. Thematic analysis of interview and focus group transcripts and recordings will again be performed using Dedoose software, using an iterative and collaborative process of coding as described in Aim 2.

Intention-to-treat analysis

Participants who “cross over” from their assigned study arm (as determined by the provider they are likely to see) will be included in the final analyses in the arm in which they were initially assigned.

Modified intention-to-treat analysis: Post-randomization exclusion

Some participants may be excluded from analysis after being randomized:

- Participants who find out they are pregnant during their enrollment visit (and thus would have been ineligible had this been known prior to enrollment).
- Participants who enrolled in the study more than once (their second enrollment will be excluded).

Additional Analyses

Intervention arm patient participants’ decision support tool data will be analyzed. Participant data input to the tool includes patient preferences around birth control characteristics, their recommended methods, and any questions for their provider.

D. Data Management

Only Key Study Personnel as approved on the UCSF CHR application will have access to study data. As much data as possible will be collected and stored electronically in order to minimize the number of pieces of paper containing PHI and the possibility for participant data to be lost or breached. Collecting data electronically also eliminates the possibility for study staff to make errors in data entry when transferring data from paper to electronic storage.

Surveys

All patient and provider surveys will be administered via REDCap using secure iPads. Survey data will then live in the secure UCSF REDCap database. All user actions in REDCap are tracked by user and time (for example, editing or downloading data). Participant names and contact information will be marked as PHI and will not be downloadable. Only de-identified data will be able to be downloaded by study

Study Protocol

Patient Centered Support for Contraceptive Decision-Making: A Cluster Randomized Controlled Trial of a Contraceptive Decision-Support Tool

November 22, 2016

staff. If downloaded to Excel or Stata for analysis, study datasets will remain on a secure UCSF server accessible only by study staff. Patient follow-up will also be tracked in REDCap.

Note: Surveys for participants who chose vasectomy as their contraceptive method at baseline and started that method will be administered over the phone using paper-based templates rather than REDCap, due to the difficulty associated with programming a survey for this specific method. Upon completion, the survey data will be manually entered into REDCap within one month and the paper-based survey will be shredded.

Consent forms

Paper consent forms and HIPAA authorizations will be stored in locked file cabinets in a locked ward for three years after study completion, according to UCSF IRB stipulations. They will not be linked to participant study IDs.

Time study

Time study data will contain no PHI other than the participant study ID. It will be tracked in an Excel spreadsheet on a secure server.

Audiorecordings and interviews

All audio recordings of patient visits and provider and staff interviews will be managed in accordance with Dr. Dehlendorf's standard operating procedures. This includes promptly transferring recordings off of the recording device and onto a secure UCSF server, having visits transcribed and de-identified in a HIPAA-compliant manner, and storing de-identified transcripts used in qualitative analysis on a secure UCSF server.