UC San Diego
Independent Study Projects

Title
Medication Safety and contraceptive counseling for Reproductive aged women with Psychiatric conditions (MSRP).

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Medication Safety and contraceptive counseling for Reproductive aged women with Psychiatric conditions (MSRP)

Independent Study Project (ISP) for Karen Levy, MS4

ISP Committee: Sheila Mody, MD MPH (chair); Christina Chambers, PhD MPH; Elizabeth Salas, MPH

Submitted March 25, 2014
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I. Rationale

There is currently limited research that addresses the unique medication safety and family planning needs among women of reproductive age with psychiatric conditions. The multidisciplinary Medication Safety and Contraceptive Counseling for Reproductive Aged Women with Psychiatric Conditions (MSRP) study conducted between the UCSD Department of Reproductive Medicine, the Gifford Clinic in the Department of Psychiatry at UCSD and the MotherToBaby California teratogen counseling service by UCSD Pediatrics seeks to better understand the feasibility of a novel individualized 1-on-1 counseling session that will help women in this population better understand: 1) which of their medications are safe to use in pregnancy, 2) provide education regarding the importance of using contraception and which contraceptive choices are available to them, and 3) raise awareness of any drug-drug interactions that may exist between their medications and their chosen method of contraception. If this study demonstrates a significant benefit to these patients, this counseling service may lead to a long-term relationship between the MotherToBaby California Project and the Gifford Psychiatric Clinic in which women seen in this clinic are routinely offered this specialized counseling.

II. Background

Nearly half of all pregnancies in the general population in 2006-2010 were unintended.\(^1\) In addition, data from the National Survey of Family Growth shows that in 2006-2010, only 62.2% of women aged 15-44 in the United States are using some form of contraception.\(^2\) These statistics inherently suggest a need for additional education in the general population regarding contraceptive options. It is unknown how these statistics for the general population apply to women with psychiatric conditions. In addition, reproductive age women with psychiatric diagnoses have several unique family planning considerations.

TERATOGENICITY OF PSYCHIATRIC MEDICATIONS:

Some women with psychiatric conditions may be on medications that are not safe for use in pregnancy and therefore may require counseling on their highly effective contraceptive options. These women may also have other environmental exposures to alcohol, tobacco and illicit drugs, so this may be an additional need for counseling about risk to a potential pregnancy. Other women in this population may become pregnant and stop using their psychiatric medications because they are unaware that their medications are safe to use in pregnancy. The United States Food and Drug Administration uses the following categories to rate the safety of using various pharmaceutical agents in pregnancy:
Most psychotropic drugs used to treat bipolar disorder are category C or D. For example, lithium, a mood stabilizer used as a first-line treatment for bipolar disorder, is associated with an increased risk of congenital cardiac abnormalities and is FDA category D for use in pregnancy. Also, valproate and carbamazapine, which are commonly used as mood stabilizers, have been associated with neural tube defects in the fetus and thus are also FDA category D for use in pregnancy.

**CONTRACEPTION:**

Women in this population may also wish to delay or avoid pregnancy due to the current state of their psychiatric condition and thus should be encouraged to use effective contraception. Women with psychiatric diagnoses may stop using contraception due to a variety of factors including: drug-drug interactions with their psychiatric medication, psychiatric hospitalization, loss of personal control over their medication administration, and preconceived notions of how contraception may impact their psychiatric condition. Long-acting reversible contraceptive (LARC) options, such as intrauterine devices (IUDs), requiring no patient compliance to achieve maximal efficacy may therefore be good options for these women. For these reasons, there may be a role for focused counseling on LARC in this population. Due to a number of barriers including physician prescribing practices and patient’s attitude towards LARC, less than 3% of women in the United States choose this method of contraception despite its proven safety and efficacy. In an effort to promote the awareness and use of LARC methods in the general population, the Contraceptive CHOICE Project offered 10,000 women aged 14-45 in the St. Louis area counseling regarding these methods and offered LARC at no cost. They found that with adequate patient education regarding the use of LARC and by removing the financial barrier, two-thirds of the women in the study chose LARC as their contraceptive.
DRUG-DRUG INTERACTIONS:

Some women with psychiatric conditions are on medications that interact with combined hormonal oral contraceptives (COCs) and may benefit from specialized counseling regarding which contraceptive options are safe for them to use. In 2010, the Centers for Disease Control and Prevention (CDC) published the United States Medical Eligibility Criteria (USMEC) in an effort to improve contraceptive safety guidance. The USMEC includes guidance on contraceptive safety for specific medications, including those commonly used to treat psychiatric illness. For example, carbamazepine, oxcarbazapine, phenytoin, and topiramate, which are commonly prescribed for mood stabilization, increase the clearance rate of oral contraceptives; thus patients receiving one of these treatments should consider switching to an alternative form of contraception. The USMEC continues to be updated and will likely prove to be a valuable resource to optimize contraceptive counseling for these women.

This multidisciplinary research project involves a unique collaboration between the MotherToBaby Project, Reproductive Medicine at UCSD and Psychiatry at UCSD to deliver individualized contraceptive and teratogen counseling to women with psychiatric conditions. MotherToBaby California, formerly known as the CTIS Pregnancy Health Information Line, in the Department of Pediatrics at UCSD provides teratogen counseling free of charge on the risks or safety of medications, chemicals, recreational drugs and alcohol, infectious or chronic disease, and medical conditions in pregnancy. The goal of MotherToBaby is to provide individualized risk assessments and referrals for further assistance or diagnostic testing to pregnant or breastfeeding women in order to prevent birth defects, as well as pregnancy and neonatal complications, related to prenatal or breastfeeding exposures. Recently, MotherToBaby has also focused on counseling non-pregnant women given the high rate of unintended pregnancy.

This study will serve to investigate the feasibility of counseling that may uncover and address unmet family planning needs of reproductive age women with psychiatric diagnoses. The proposed project also promotes the utilization of the USMEC contraceptive guidance from the CDC which has been endorsed by the American Congress of Obstetricians & Gynecologists and American Academy of Family Physicians.

III. Specific Aims

The MSRP study has three main objectives:

1: Assess patient knowledge
   - Determine baseline patient knowledge of medication safety in pregnancy and contraceptive options among reproductive aged women with psychiatric conditions.
   
   Hypothesis: Women with psychiatric conditions will have limited baseline knowledge of medication safety in pregnancy, teratogens, drug-drug interactions and contraceptive options.

2: Assess family planning needs
   - Determine if there is un-meet need for family planning among women with psychiatric conditions.
   - Study the utilization of contraception among women with psychiatric conditions.
Hypothesis: Women with psychiatric conditions use less contraception compared to the general population.

3: Intervention

- Assess whether focused education on medication safety and contraceptive choices impacts patient knowledge.

Hypothesis: Specialized counseling on medication safety will lead to improved knowledge about teratogens, and contraception.

IV. Methods

The MSRP study is a cross-sectional study of reproductive age women (18-50 years old) with psychiatric conditions seen at Gifford Clinic in the UCSD Psychiatry Department. A complete description of the inclusion and exclusion criteria provided in Appendix A.

Women seen at a psychiatric follow-up visit are offered the option to participate in this study. If they choose not to participate, this decision does not impact their care. The women who choose not participate receive standard of care counseling. Those women who chose to participate in the study receive a 1-on-1 counseling session with a MotherToBaby counselor.

Participation in the study is completed in a single session and involves: informed consent, a post-consent instrument to assess whether or not the patient understands the consent form, a pre-counseling questionnaire, a pre-counseling quiz, an individualized counseling session with one of the Mother-To-Baby counselors, a post-counseling quiz and finally a post-counseling questionnaire. The pre-counseling questionnaire assesses which type of contraception the participants are using and explores their reasons for choosing this method. The pre-counseling quiz assesses their baseline level of knowledge regarding medication safety and contraceptive options. Specifically, they are queried on their knowledge of IUDs and the contraceptive implant to assess their awareness and preconceived notions regarding these options.

The participants are then counseled by a MotherToBaby counselor regarding the safety of their medications for use in pregnancy. If a participant is on medications that are safe in pregnancy, she is told this and encouraged to continue the medication in the event that she became pregnant. If the participant is on a medication that is a teratogen, she is educated about the importance of using contraception. For example, if a participant is on lithium she is told about the risks to the fetus if she were to become pregnant and explained the importance of using contraception while taking this medication. If this participant expresses the desire to become pregnant despite being on this medication, she is instructed to speak to her psychiatrist.

Drug-drug interactions between psychiatric medications and birth control methods are also addressed by the MotherToBaby counselor. For example, common mood stabilizer medications, such as carbamazepine, interact with combined hormonal contraceptive pills.

All participants are required to watch an approximately 10 minute video entitled "The Contraceptive Choice Project: Which Birth Control Method is Right for You?" by Washington University in St. Louis.12 This video can be found on YouTube at the following URL: http://www.youtube.com/watch?v=u9SHoy1C3tU
This video provides basic education regarding various reversible forms of birth control including IUDs, contraceptive implant, Depo-Provera shot, estrogen and progesterone-containing contraceptive options (vaginal ring, patch or oral combination pills), progestin-only forms of contraception, condoms, and emergency contraception. The video addresses effectiveness, administration, duration, contraindications, side-effects, drawbacks and describes the type of patient who is an ideal candidate for each method.

The patients are then given a post-counseling quiz to assess whether the specialized counseling impacted their understanding of medication safety and contraceptive options. Afterwards, they are given a post-counseling questionnaire to assess their contraceptive plans and their satisfaction with the counseling.

The study is planned for one year from design to completion and counseling sessions officially began March 3, 2014. Based on the number of patient visits to Gifford clinic annually, it is estimated that approximately 200 women of reproductive age with psychiatric diagnoses may meet criteria for participation in the study. It is estimated that approximately 100 will participate in this study at its completion.

Descriptive statistics will be calculated for all demographic variables. Chi-square analyses will be used to evaluate the difference between study population and national population. The national data will be obtained from the National Survey on Family Growth. Change from pre to post knowledge gained will be assessed using the paired t-tests. Significance was defined as $p < 0.05$.

V. Feasibility

A) Barriers in Implementation of MSRP Study

The concept for the multidisciplinary MSRP study was introduced in spring of 2013, and a research team was selected through several meetings between faculty members in the Department of Reproductive Medicine (Dr. Sheila Mody), the Department of Psychiatry (Dr. Katie Hirst), and the MotherToBaby counseling service (Dr. Christina Chambers). Our initial plan was to begin conducting the counseling sessions in August 2013; however, several unforeseen barriers resulted in a 7-month delay of beginning the study. The Institutional Review Board (IRB) approval process was initiated in May 2013 and took over 3 months with several revisions. Once we obtained IRB approval, we were informed that we would need approval from San Diego County Behavioral Health Services (SDBHS) in order to conduct counseling sessions at the UCSD Gifford Psychiatric Clinic. The SDBHS approval process took another two months and required submission of additional paperwork and meeting with the SDBHS board. This meeting is only once a month. Once we obtained County approval in November 2013, we needed support from the Gifford Clinic leadership to start the study. We also needed to meet with the Gifford Clinic Manager again to conduct a site visit and solidify the logistics of where/how the counseling sessions will be conducted. This entire process of seeking the necessary approvals and sorting out the logistics pushed our start date from the initially anticipated August 2013 to March 2014.

B) Literature Review of Barriers to Collaborative Clinical Research

The MSRP study targets a population in need of research to inform the programmatic development on reproductive health counseling. The paucity of information concerning the specific family planning needs of women with psychiatric conditions further demonstrates this need. The very nature of this study requires a collaborative effort between a multidisciplinary team of healthcare professionals and others,
including: principal investigators from each of the departments represented, physicians and staff at the Gifford clinic who help recruit patients, counselors to conduct the study, a research coordinator, students involved in designing the project and data collection, support of the ancillary staff at the clinic, and perhaps most importantly, informed patients who volunteer to participate as research subjects. It has been well documented that this type of multidisciplinary collaborative research presents unique challenges, a few of which are directly applicable to the MSRP study and will be discussed here:

1. Participant Recruitment

Recruitment of research subjects is one of the most challenging parts of a clinical research study as most trials never meet their recruitment goal and that the greatest challenge is publicizing to potential subjects.\(^8\)\(^,\)\(^1\)\(^1\) A 2003 paper from the journal *Advances in Psychiatric Treatment* by Patel *et al* discusses the many potential pitfalls in the identification and recruitment of subjects for psychiatric research. This paper suggests that the goals of recruitment should include: A) to recruit a sample that represents the target population and B) to recruit a large enough sample size to meet the power requirements of the study. To address these goals, the inclusion criteria for the MSRP study was carefully selected to include a representative sample from the Gifford Clinic that broadly reflects the greater population of reproductive aged women with psychiatric conditions. In addition, sample size was determined using a power calculation discussed in more detail in 'Methods'.

The physical recruitment of these potential candidates can be one of the greatest challenges.\(^8\) There are many reasons why patients would not want to participate in a clinical study, a few examples include: time constraints, lack of understanding of the importance of the study, fear that participating in research will harm them in some way, and risk of being placed in a placebo group (if applicable). Several steps were taken in designing the MSRP study to mitigate some of these barriers, including: A) a thorough informed consent, B) a small financial incentive, and C) designing the study as a cross-sectional study (all data collected at a single point in time with no follow-up) rather than studying a cohort over time in an attempt to make recruitment easier and require minimal time commitment from the participants.\(^8\)

One strategy to enhance recruitment of participants is to continually approach those who choose not to participate initially. Patel 2003 suggested that subjects are most likely to participate on the initial prompt, and about half of subsequent attempts to recruit those who initially decline are successful. An example of this strategy for recruitment, called "assertive tracking" is summarized as follows:
In addition to this, most patients find out about current clinical research studies from their physicians which makes physician awareness and acceptance of the study paramount in recruitment. A few examples of physician barriers to clinical research recruitment are: lack of awareness that the trial is going on, lack of time to discuss the trial with patients, and a concern that the clinical trial will be burdensome to patients. Open communication and collaboration, discussed next, may strengthen the physician-study relationship and indirectly improve recruitment yields.

2. Working with Other Clinicians

Research of human subjects almost always requires working with other health care professionals. The ability to recruit participants requires close collaboration between the study administrators and the clinicians involved in advertising the study to their patients. Identifying clinicians at the site(s) you are studying who are supportive of research and asking permission early on in the planning of the study will help strengthen the collaboration between clinicians and the study administrators.

Patel recommends that the principal investigator (PI) make an appearance at early stages of recruitment to help facilitate the recruitment process and help all of the practitioners and ancillary staff at that site better appreciate the purpose and integrity of the study. They also recommend frequently considering the question, "What can I do for the collaborators so that they will refer patients to the study?" A few techniques to accomplish these goals are summarized as follows:
3. Increased Regulatory Burden

As described in previous sections, the series of approvals required to begin the MSRP study pushed the anticipated start date back by seven months. The Institutional Review Board (IRB) approval process took about 3 months from the initial submission to its approval with several revisions, and only after IRB approval was obtained could approval from the County be sought after. All required approvals, outlined in the next section, needed to be obtained prior to beginning the study. Given that this study does not require use of an experimental drug and has an overall minimal risk to its participants, this process took much longer than expected.

The current literature on this topic suggests that increased regulatory burden as a barrier to conducting clinical research is not unique to this study. In a publication by Schlaff, the authors discuss the length and requirements of IRB submission have greatly increased in recent years.\textsuperscript{10} This study utilized data from the institutional reviews of two multicenter clinical trials for the treatment of infertility in women with polycystic ovarian syndrome (PPCOS I initiated in 2002 and PPCOS II initiated in 2009) to compare the total length of the IRB submission process and the length of the patient consent form at a total of 4 clinical sites that participated in both studies. They found that, in those 7 years, the length of the IRB submission and patient consent form nearly doubled. They also observed that there was variability in how the individual IRBs evaluated the studies; however, none of the boards required significant changes to the clinical protocols.\textsuperscript{10}

In 2011, Legro published that at Penn State School of Medicine, the IRB approval takes on average 3-4 months assuming no major objections.\textsuperscript{11} Legro goes on to discuss that his research involves two vulnerable populations, pregnant women and their fetuses, which greatly increases the regulatory burden because the IRB often feels that any research involving pregnancy is too risky. Somewhat paradoxically, these regulations that are meant to protect patients vastly decrease the body of evidence that is available to treat patients in this population. Legro suggests a couple of solutions to make the research process more productive and efficient: A) eliminate the concept of labeling a population as "vulnerable" and instead consider each individual study's unique risks, and B) incorporate use of common sense into streamlining the process of grant and protocol submission to regulatory bodies.\textsuperscript{11}
VI. Discussion

The initial counseling sessions were conducted in mid-March 2014; therefore, there is no data to report at this time. A brief description of the study design and some of the anticipated limitations discussed here:

A. Generalizability

In order to make the study as feasible as possible, we chose to focus on a very specific population of English-speaking subjects that met our inclusion criteria at one outpatient clinic. Our data, therefore, will only reflect this population, and it will be unclear how this data reflects the needs of the broader population of reproductive-aged women with psychiatric conditions. A more complete representative sample of this population may have included several clinics in a variety of inpatient and outpatient settings and a sub-focus on recruiting ethnic minorities, non-English-speakers, low socioeconomic status, and cognitively impaired patients.

B. Control Group

The MSRP study uses standardized questions and data from the National Survey of Family Growth that represents a very large sample of women of reproductive age as a control for our data regarding utilization of contraception in this population. We are not studying 'normal' healthy participants in this study, however, to directly compare our results from women with psychiatric conditions to those without. All participants will receive the exact same questionnaires, quizzes and counseling, so there is not an internal control group in this study. However, the main purpose of this study is to demonstrate feasibility of this type of counseling and our cross-sectional design should address that question adequately.

C. Study Design

A cross-sectional study design was chosen in order to simplify the study by requiring only one data point, therefore aiding in recruitment of subjects. Additionally, this study design eliminates the concern that psychiatric patients may be difficult to reach for follow-up study questionnaires. The limitation to this is that we will only know the immediate effect of our intervention on patient knowledge of contraceptive choices, drug-drug interactions and teratogenicity of their medications. Whether they make any behavioral changes in these areas will not be known. Though less feasible, a cohort study may have been a more appropriate study design in order to include data on how our intervention affects behavior at regular intervals. A cohort study would require a long commitment from the participants with a significant amount of follow-up, so this type of study would be costly and would have the potential for a high rate of lost to follow-up.

VII. Student Involvement

I joined the research team in April 2013 and helped draft the initial IRB proposal including all of the supporting documents (e.g. questionnaires, quizzes, informed consent, and recruitment flyer) represented in the Appendix. This study represents my first clinical research project and my first attempt at an IRB submission. I also attended the monthly MSRP team meetings in early 2013 where I participated in the initial design, coordination and planning for the study. When the IRB had been approved, I worked on keeping the documents current by attending
future team meetings and helping submit amendments when appropriate. Lastly, I have attended one of the initial
recruitment and counseling sessions at Gifford Clinic in March 2013.

This project helped me develop an appreciation for the complexity of designing a clinical research study
and to discover a number of barriers to implementing a study once it has been designed. The process took a
considerable amount of time beyond what was initially expected by the research team and was a valuable lesson in
the feasibility of clinical research as previously discussed. In addition, I learned how to approach drafting an IRB
submission and how to obtain true informed consent from potential research subjects, both of which will greatly
benefit my future clinical research endeavors.

VIII. References


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   16: 263-72

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    Fertility and Sterility. October 201. 96(4): 817-819

    contraception. Amer J Obstet Gynecology. August 2010
**Appendix A: Participant Selection**

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age of participants: 18-50 years old</td>
<td>Planning to become pregnant</td>
</tr>
<tr>
<td>Gender of participants: Female</td>
<td>Not sexually active with men</td>
</tr>
<tr>
<td>Presenting for a follow-up psychiatric visit</td>
<td>History of hysterectomy, bilateral oophorectomy or surgical sterilization</td>
</tr>
<tr>
<td>Ethnic background: will only include English-speaking participants as MotherToBaby counselors are only able to speak English</td>
<td>Decisionally impaired- Please see the post-consent instrument to assess decisional capacity. If a potential participant does not score 100% on the post-consent instrument, then she is excluded from participation</td>
</tr>
<tr>
<td>Level of education: no limitation</td>
<td></td>
</tr>
<tr>
<td>Health Status: at least one psychiatric condition for which they are taking medication</td>
<td></td>
</tr>
<tr>
<td>Sexually active with men</td>
<td></td>
</tr>
</tbody>
</table>
Appendix B: Participant Consent

University of California, San Diego
Consent to Act as a Research Subject
Medication Safety and contraceptive counseling for Reproductive aged women with Psychiatric conditions (MSRP)

Sheila Mody, MD MPH, Katie Hirst, MD, and Christina Chambers PhD MPH are conducting a research study to find out more about the unique medication safety and family planning needs among women with psychiatric conditions. You have been asked to participate in this study because you are a female between ages of 18 and 50 who is currently taking at least one psychiatric medication. The purpose of this study is to develop specialized counseling about contraceptive use, the safe use of psychiatric medication during pregnancy, and the effects of birth control pills on psychiatric medications. There will be approximately 100 participants total enrolled in this study from the Gifford Clinic. Please take your time to make your decision and be sure to ask any questions that you may have.

What is involved in this study?
After your appointment with your psychiatrist today, you will have a counseling session with a trained counselor. First you will be asked to complete a short questionnaire about what type of birth control you are currently using. This questionnaire should take less than 5 minutes to complete. You will then be given a short 10-question quiz about your knowledge of birth control and medication safety. The quiz should also take you less than 5 minutes to complete, and you will not be given your results on the quiz. Next, you will have a short counseling session with a counselor who will discuss your psychiatric medications with you and any potential risks of using these medications during pregnancy. This session should take 10 minutes or less. You will then watch an approximately 10-minute video about various birth control options. At the end of the session, you will retake the quiz. The total time to complete the study should be about 30 minutes, all of which will be completed in a single session. The alternative to participating is to receive the standard of care which is no counseling session.

What risks are associated with this study?
Participation in this study may involve some added risks or discomforts. These include feeling uncomfortable answering questions about your sexual behaviors and health history. You can choose not to answer any questions that make you feel uncomfortable. We will make every reasonable effort to keep your records confidential. Because this is a research study, there may be some risks that are currently unknown. You will be informed of any significant new findings.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. We will keep all research records for this project in locked files or computer files that can only be opened with a password. We will use study ID numbers in place of your name to identify the data collected and will store the list that links your name and other personal information to the study ID number separately from research records. We will never use your name or personal information that could be used to identify you in any journal articles or reports. All potentially identifying participant information will be destroyed in a secure manner after the completion of the study. Research records may be reviewed by the UCSD Institutional Review Board.

What benefits can be reasonably expected?
There may or may not be any direct benefit to you from this study. The investigator(s), however, may learn more about effective methods of educating women on psychiatric medication safety and birth control. Based on what you learn in the study you may choose to make an appointment with your physician to learn more about your birth control method(s) and options.
Can you choose to not participate or withdraw from the study without penalty or loss of benefits? Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. The alternative to participating in the study is to not participate and not receive the focused medication safety and contraceptive counseling. Your decision to participate or refuse participation in this study will in no way impact your medical care. If you would like to withdraw from the study, please inform the counselor/research assistant.

Can you be removed from the study without your consent? You may be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study? You will receive a $10 gift card for participating in this study. You will receive this gift card at the completion of study part participation (the same day as counseling).

Are there any costs associated with participating in this study? There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study? If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 657-5100 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

Who can you call if you have questions? If you have other questions or research-related problems, please contact: Sheila Mody, MD MPH at (858) 246-1740 University of California, San Diego

What are your rights as a research subject? Taking part in this study is entirely voluntary. You may choose not to take part or you may choose to leave at any time. This decision will not result in any penalty or loss of any benefits to which you are entitled, including the quality of care. If you have questions about your rights you may call the Human Research Protections Program Office at (858) 657-5100 at any time.

Your Signature and Consent
You have received a copy of this consent document and a copy of the “Experimental Subject’s Bill of Rights” to keep. By signing below you agree to participate in this research study.

Printed name of subject _____________________ Birth date ______________

Subject’s signature _______________________ Today’s date ______________

Witness signature _________________________ Today’s date ______________

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Version 06/12

Human Research Protections Program

UC San Diego

Approved Initial Approval: 09/22/2013
Current Approval: 09/22/2013
Do not use after: 09/21/2014
Appendix C: Post-consent Instrument

Instructions: For each of the following questions, please choose one answer.

1) The reason why the researchers are doing this study is to:
   a. Find out more about the family planning needs of women who take medications for mental conditions
   b. Determine if medications are affected by smoking
   c. I don’t know.

2) It's okay if I decide I don’t want to participate?
   a. Yes, Participation is voluntary.
   b. No, I must participate

3) During this session, I will be asked to:
   a. Take a short questionnaire about my general health and birth control use
   b. Receive counseling on my medication(s)
   c. Watch a short video on birth control
   d. Take a quiz at the end
   e. Answers A through D are correct
   f. I’m not sure what is involved in this study

4) The possible risks of participating are:
   a. I might feel a little uncomfortable being asked about birth control and my health history.
   b. I’m not sure.

5) The researchers will keep all the information I share confidential, to the best of their ability.
   a. True
   b. False
Appendix D: Pre-counseling questionnaire

Instructions: Please fill out the following form by selecting the one best option unless where otherwise instructed.

Section 1: Demographics

1. What is your age?
   ____ years

2. What is your height?
   ____ feet  ____ inches

3. What is your weight?
   ____ pounds

4. What primary language do you speak at home?
   A. English
   B. Spanish
   C. Other _________________________

5. What is your race or ethnicity?
   A. White
   B. Black
   C. Hispanic
   D. Asian/Pacific Islander
   E. Indian/Native American

6. What is your marital status? (Please choose one option below)
   A. Single
   B. Married
   C. Divorced
   D. Separated
   E. Widowed

7. What is your employment status? (Please choose one option below)
   A. Full time employed
   B. Part time employed
   C. Self Employed
   D. Student
   E. Housewife
   F. Unemployed

8. What is your highest degree level?
   A. High school diploma/GED
   B. Associate’s Degree
   C. Bachelor’s Degree
   D. Master’s Degree
   E. Doctorate Degree
   F. None
9. Please indicate if you have any of the following medical conditions. (Choose all that apply)

A. Diabetes  
B. High blood pressure  
C. High Cholesterol  
D. Heart disease  
E. Other __________________________

10. Do you have any of the following psychiatric conditions? (Please choose all that apply)

A. Bipolar disorder  
B. Mood disorder, unspecified  
C. Depression  
D. Schizophrenia  
E. Psychotic disorder, unspecified  
F. Other __________________________

11. What psychiatric medications are you currently taking? (Please choose all that apply)

Abilify (Aripiprazole)  
Lexapro (Escitalopram)  
Thorazine (Clorpramazine)  
Ativan (Lorazepam)  
Lithium  
Topomax (Topiramate)  
Celexa (Citralopram)  
Luvox (Fluvoxamine)  
Trileptal (Oxcarbazepine)  
Clozaril (Clozapine)  
Paxil (Paroxetine)  
Trazadone (Desyrel)  
Depakote/Divalproex (Valproic Acid)  
Prozac (Fluoxetine)  
Valium (Diazepam)  
Haldol (haloperidol)  
Restoril (Temazepam)  
Wellbutrin (Bupropion)  
Klonopin (Clonazepam)  
Seroquel (Quetapine)  
Xanax (Alpraxolam)  
Lamotrigine (Lamictal)  
Tegretol (Carbamazepine)  
Zoloft (Sertaline)  
Other __________________________

Other __________________________

Other __________________________

12. Do you smoke cigarettes?

A. No  
B. Yes, < 15 cigarettes/day  
C. Yes, > 15 cigarettes/day  

13. Do you drink alcohol?

A. No  
B. Yes, 1-6 drinks in one week  
C. Yes, 5 or more drinks in one day  
D. 7 or more drinks in one week  

Section 2: Preconception Health/Family Planning
The next set of questions asks you about your thoughts and experiences with family planning. Please remember that all of your answers will be kept confidential.

1. Has a doctor, nurse, or other health care worker ever talked with you about ways to prepare for a healthy pregnancy and baby during a routine health visit, not including prenatal visits?

   A. Yes
   B. No
   C. Don’t know / Not sure

2a. Have you ever been pregnant?

   A. Yes (please go to question 2b)
   B. No (please go to question 3)
   C. Don’t know / Not sure

2b. How many times have you been pregnant? ____________

2c. Please indicate the outcome of your prior pregnancies and specify the date

<table>
<thead>
<tr>
<th>Pregnancy 1: Month _____ / Year _____</th>
<th>Pregnancy 2: Month _____ / Year _____</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Live birth</td>
<td>A. Live birth</td>
</tr>
<tr>
<td>B. Miscarriage</td>
<td>B. Miscarriage</td>
</tr>
<tr>
<td>C. Termination</td>
<td>C. Termination</td>
</tr>
<tr>
<td>D. Ectopic Pregnancy</td>
<td>D. Ectopic Pregnancy</td>
</tr>
<tr>
<td>E. Stillbirth</td>
<td>E. Stillbirth</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pregnancy 3: Month _____ / Year _____</th>
<th>Pregnancy 4: Month _____ / Year _____</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Live birth</td>
<td>A. Live birth</td>
</tr>
<tr>
<td>B. Miscarriage</td>
<td>B. Miscarriage</td>
</tr>
<tr>
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</tr>
<tr>
<td>E. Stillbirth</td>
<td>E. Stillbirth</td>
</tr>
</tbody>
</table>

3. Did you or your husband/partner do anything the last time you had sex to keep you from getting pregnant? (Please choose all that apply)

   A. Yes (go to question 4b)
   B. No (please go to 4a)
   C. No partner/not sexually active
   D. Same-sex partner
   E. Don’t know / Not sure

4a. If you indicated above that you did not use anything to keep you from getting pregnant the last time you had sex, please indicate why: (Choose all that apply)

   A. Trying to become pregnant
   B. Unable to pay for birth control
   C. Too difficult to obtain birth control
   D. Unsure about what birth control options are available
   E. You do not want to use hormones
   F. You or your partner don’t want to use birth control
   G. You do not think you can become pregnant

4b. What did you or your husband/partner do the last time you had sex to keep you from getting pregnant? (Please choose all that apply)
A) Female sterilization (ex. tubal ligation, Essure, Adiana)  
B) Male sterilization (vasectomy)  
C) Contraceptive implant (ex. Implanon or Nexplanon)  
D) Hormonal intrauterine device (IUD) (ex. Mirena, Skyla)  
E) Copper intrauterine device (IUD) (ex. ParaGard)  
F) Shots (ex. Depo-Provera)  
G) Combined Hormonal pills (estrogen and progesterone)  
H) Progestin-only pill (mini-pill)  
I) Birth control pills, unspecified  
J) Contraceptive patch (ex. Ortho Evra)  
K) Contraceptive ring (ex. NuvaRing)  
L) Condoms  
M) Diaphragm, cervical cap, sponge  
N) Not having sex at certain times (rhythm or natural family planning)  
O) Withdrawal (or pulling out)  
P) Spermacidal foam, jelly, film, or cream  
Q) Douches  
R) None of the Above

4c. If you are currently using birth control, what do you think is the typical use failure rate for the method of birth control that you are currently using?
A. Less than 1% chance of pregnancy  
B. 1-5% chance of pregnancy  
C. 6-10% chance of pregnancy  
D. Greater than 10% chance of pregnancy  
E. Don't know

4d. What was the biggest influence on which contraceptive method you choose?  
(Please choose all that apply)  
A. Cost  
B. Effectiveness in preventing pregnancy  
C. Safety of the method given my medical condition  
D. Avoiding hormones  
E. Other _______________________

5. How do you feel about having a child now or sometime in the future? Would you say:  
A. You don't want to have one  
B. You do want to have one, less than 12 months from now  
C. You do want to have one, between 12 months to less than 2 years from now  
D. You do want to have one, between 2 years to less than 5 years from now  
E. You do want to have one, 5 or more years from now  
F. Don't know/ Not sure

6. If you were taking your current medications and unexpectedly became pregnant, what would be your next step? (Choice one answer)
A. Stop taking your medications, since you do not know if the medication is safe to use in pregnancy
B. Ask a psychiatrist if the medication is safe to use in pregnancy
C. Ask an obstetrician/gynecologist if the medication is safe to use in pregnancy
D. Ask a primary care doctor if the medication is safe to use in pregnancy
E. Continue the medication and do not ask a physician if the medication is safe to use in pregnancy
F. Reduce dosage of medications
G. Stop some medications and continue others
H. Go online to research what to do
Appendix E: Pre- and Post-counseling quiz

Instructions: For each of the following questions, please choose one answer.

1. Which of the following is the **MOST** effective form of birth control?
A. Birth control pills
B. Intrauterine Devices
C. Contraceptive Injections
D. Condoms

2. Which of the following forms of birth control is the shortest acting?
A. Birth control pills
B. Contraceptive Injections
C. Contraceptive Implants
D. Intrauterine Devices

3. In the general population, what percentage of women using intrauterine devices will get pregnant in a year?
A. Less than 1% chance of pregnancy
B. 1-5% chance of pregnancy
C. 6-10% chance of pregnancy
D. Greater than 10% chance of pregnancy

4. In the general population, what percentage of women using condoms will get pregnant a year?
A. Less than 1% chance of pregnancy
B. 1-5% chance of pregnancy
C. 6-10% chance of pregnancy
D. Greater than 10% chance of pregnancy

5. Which of the following medications are safe to use in pregnancy?
A. Paroxetine (Paxil)
B. Sertraline (Zoloft)
C. Olanzapine (Zyprexa)
D. All of the above

6. All of the following medications may cause birth defects, **EXCEPT**?
A. Lithium
B. Fluoxetine (Prozac)
C. Carbamazepine (Tegretol)
D. Valproic acid (Depakote)

7. Which vitamin is especially important for women take if she is taking a medication that may cause neural tube birth defects?
A. Vitamin D
B. Folic Acid
C. Vitamin C
D. Vitamin B12

8. If a woman is unsure whether her medications were safe to use in pregnancy and she became pregnant, all of the following would be appropriate actions **EXCEPT**?
A. Stop taking the medications, since she does not know if the medication is safe to use in pregnancy
B. Ask a psychiatrist if the medication is safe to use in pregnancy
C. Ask an obstetrician/gynecologist if the medication is safe to use in pregnancy
D. Ask a primary care doctor if the medication is safe to use in pregnancy

9. Which type of birth control lowers the effectiveness of the mood stabilizer Lamotrigine (Lamictal)?
A. Combined oral contraceptives
B. Intrauterine Devices
C. Contraceptive Implants
D. Contraceptive injections

10. All of the following medications have drug-drug interaction with combined birth control pills, **EXCEPT**?
A. Lithium
B. Lamotrigine (Lamictal)
C. Carbamazepine (Tegretol)
D. Topiramate (Topomax)
Appendix F: Post-counseling questionnaire

Instructions: For the following statements 1-5, please indicate how strongly you agree. For questions 6-8, please choose the best answer from the list provided.

1. I know if I am taking a medication that may not be safe for use in pregnancy due to harmful effects on a developing fetus.
   
<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
</table>

2. I understand how to protect myself against getting pregnant while taking a medication that may not be safe to use in pregnancy.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
</table>

3. I understand the potential drug-drug interactions between my method of birth control and my psychiatric medication(s).

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
</table>

4. As a result of the counseling session today, I am more likely to speak to my doctor about choosing a birth control option that fits my needs.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
</table>

5. As a result of the counseling session today, I am more accepting of long-acting reversible forms of birth control, such as the contraceptive implant or intrauterine device.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
</table>

6. What do you plan to use the next time you have sex to keep you from getting pregnant? (Please choose all that apply)

   A. Female sterilization (ex. tubal ligation, Essure, Adiana)
   B. Male sterilization (vasectomy)
   C. Contraceptive implant (ex. Implanon or Nexplanon)
   D. Hormonal IUD (ex. Mirena)
   E. Copper IUD (ex. ParaGard)
   F. Shots (ex. Depo-Provera)
   G. Combined Hormonal pills (estrogen and progesterone)
   H. Progestin-only pill (mini-pill)
   I. Birth control pills, unspecified
   J. Contraceptive patch (ex. Ortho Evra)
   K. Contraceptive ring (ex. NuvaRing)
   L. Condoms
   M. Diaphragm, cervical cap, sponge
   N. Not having sex at certain times (rhythm or natural family planning)
   O. Withdrawal (or pulling out)
   P. Foam, jelly, film, or cream
   Q. None of the Above

7. What will be the biggest influence on which contraceptive method you choose? (Please choose all that apply)

   A. Cost
   B. Effectiveness in preventing pregnancy
   C. Safety of the method given my medical condition
   D. Avoiding hormones
   E. Other ___________________
8. If you were taking your current medications and unexpectedly became pregnant, what would be your next step?

A. Stop taking your medications, since you do not know if the medication is safe to use in pregnancy
B. Ask a psychiatrist if the medication is safe to use in pregnancy
C. Ask an obstetrician/gynecologist if the medication is safe to use in pregnancy
D. Ask a primary care doctor if the medication is safe to use in pregnancy
E. Continue the medication and do not ask a physician if the medication is safe to use in pregnancy
Now Recruiting for a Study: Medication Safety and Contraceptive Counseling for Reproductive Aged Women with Psychiatric Conditions

We want to find out more about the unique medication safety and family planning needs among women with psychiatric conditions.

You can participate in this study if you are:
- Women aged 18-50
- Sexually active
- Not currently pregnant
- Taking at least one psychiatric medication
- English-speaking

What is involved in this study?
You would participate in one 30-min counseling session after your appointment with your psychiatrist.

Study participants will receive a $10 gift card to thank them for their time.

What are the possible benefits for participants?
- You will learn about the safety of your psychiatric medications and any drug interactions that your medications may have with birth control

To participate in this research study or for more information, ask your psychiatrist today or contact us at MSRPstudy@gmail.com.