RUTGERS
Robert Wood Johnson Medical School

Division of Complex Contraception and Family Planning
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Rutgers, The State University of New Jersey
125 Paterson Street
New Brunswick, NJ 08901

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study:

Music to Reduce Patient Reported Pain During Intrauterine Device (IUD) Placement in the Office

Principal Investigators:

Dr. Glenmarie Matthews, MD
Dr. Amy Patel, MD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to test the effects of music on the pain and anxiety reported during the insertion of a long acting reversible contraceptive method (LARC). This specific research seeks to determine the effects of music on the pain and anxiety traditionally experienced during and after an IUD (intrauterine device) insertion. If you take part in the research, you will be asked to fill out an initial questionnaire and respond to specified pain scales before, during, and after the IUD placement. Your time in the study will take an estimated additional of 20 minutes to the standard appointment for an IUD placement.

Possible harms or burdens of taking part in the study may be the inconvenience of the additional 20 minutes added to a participant's appointment and possible benefits of taking part may be a decrease in pain and anxiety commonly associated with LARC insertions.

An alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Dr. Glenmarie Matthews is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Glenmarie Matthews may be reached at glenmarie.matthews@rutgers.edu. Dr. Amy Patel may be reached at ajp323@rwjms.rutgers.edu. The principal investigator's address is 125 Patterson Street New Brunswick, NJ 08901 and phone number is 732 235 7755.

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?
The purpose of this study is to test the effects of music on the pain and anxiety reported during the insertion of a long acting reversible contraceptive method (LARC). The effects of music have been tested previously on patients undergoing chronic diagnoses. The team anticipates that the randomized patients that have been selected for this research will show a decrease in associated pain commonly experienced with IUD placement. The effects should last throughout the duration of and after the procedure. The expected outcome should be an approximate 25% decrease in overall pain and anxiety experienced.

Who may take part in this study and who may not?
The inclusion criteria for this study are (1) Women who have an appointment for IUD insertion at either RWJ or RMG AND(2) Women who are able to read and write in English or Spanish AND (3) Age equal to or greater than 18 years.

Why have I been asked to take part in this study?
You have been asked to take part in this study because you fit the criteria for candidates receiving Long Acting Reversible Contraction (LARC). Your participation will factor into the data that will determine whether or not music will work to suppress/reduce pain and anxiety associated with the placement of a specified LARC method.

How long will the study take and how many subjects will take part?
Your participation in this study will be the length of the standard IUD placement procedure with the addition of approximately 20 minutes to accommodate for answering of questionnaire and survey questions and data collection by the research team. The total study will take approximately 1 to 2 years of data collection and approximately 96 subjects will participate in total.

What will I be asked to do if I take part in this study?
You will be asked to fill out a brief survey before participating in this study which helps the research team document your eligibility as well as baseline measurements to compare. You will be asked to take 600 mg of a standard over-the-counter pain reliever (motrin or ibuprofen) at least 30 minutes prior to your visit. If selected, you will also be given a non-noise canceling headset that will play music during the procedure. A member of the research team will be recording answers given on a visual analog scale (VAS) at multiple points during the study. These points are, before the procedure, point of speculum placement, point of tenaculum placement, point of IUD insertion, and 5 minutes after IUD placement. No video or photographs will be taken during this study.

What are the risks of harm or discomforts I might experience if I take part in this study?
There are no risks of harm with participating in this research study. There is also no added discomfort to the placement of the IUD aside from the slight discomfort commonly associated before the use of pain relieving measures, including music in this research. As participants' names are on the consent form, there is a potential risk of breach of confidentiality.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may be that the question of whether or not music will significantly reduce associated pain and anxiety with IUD insertion will be answered. The team anticipates that the randomized patients that have been selected for this research will show a decrease in pain and anxiety with the use of intraoperative music therapy. Expected outcome should be an approximate 25% decrease in overall pain and anxiety experienced. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
There are no alternative treatments available. Your alternative is to not take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take Part in this study?
No, there is no cost to participating in this research study.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Any information gathered throughout this study that is connected to you or that an identify you in any way will remain confidential. Permission will be requested for the disclosure of any confidential material. The data will be stored on a hospital encrypted device.

What will happen to my information or biospecimens collected for this research after the study is over?

- The information collected about you for this research will not be used by or distributed to investigators for other research.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to:
Dr. Amy Patel
125 Patterson Street New Brunswick, NJ 08901

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Who can I contact if I have questions?
If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. Glenmarie Matthews, Department of Obstetrics and Gynecology, 732 235 7755.

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: New Brunswick/Piscataway HealthSci IRB 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901, (732)235-9806

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____