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INTERVENTIONAL RESEARCH PROTOCOL TEMPLATE

(HRP-503a)

STUDY INFORMATION

- **Title of Project:**

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

- **Principal Investigator Name**
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- **Protocol Version and Date:**
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1.0 Research Design

1.1 Purpose/Specific Aims

The purpose of this study is to determine if music is an effective pain management strategy during IUD insertion.

A. Objectives

This study will determine if pain and anxiety scores are lower in subjects with music versus controls without music during IUD insertion.

B. Hypotheses / Research Question(s)

This study hypothesizes that music will decrease pain during IUD insertion. We also hypothesize that music will decrease anxiety during IUD insertion.

1.2 Research Significance

Throughout the United States, long acting reversible contraceptive (LARC) methods are becoming increasingly popular. According to ACOG, 11.6% of women use LARCs, with 10.3% using intrauterine devices (IUDs) and 1.3% using the contraceptive implant (ACOG, 2017). As LARCs become more common, so should the awareness of difficulties with their insertion. Pain is one of the most frequent complaints regarding insertion among LARC users. Compared to implant users, more IUD users reported insertional pain (80% vs 18%, $p<0.0001$) and less satisfaction with pain management (72.4 vs 85.6, $p=0.04$) (Callahan, 2019).

Very few strategies to minimize pain during LARC placement have been successful. Many providers advise women to take motrin or advil prior to their IUD insertion appointment. However, administration of ibuprofen prophylaxis prior to IUD insertion has not been shown to decrease pain at the time of insertion. (Chor, 2012). Another method that has been explored is a lidocaine block. A randomized control trial of 95 women concluded that a 1% lidocaine paracervical nerve block reduces pain during IUD insertion compared with a sham block with pressure on the vaginal epithelium ($p< 0.001$) (Akers, 2017). Other measures to manage pain and increase satisfaction with LARC insertion remain largely unstudied.

This study proposes that music may be effectively used as a pain management strategy. A metaanalysis of 97 randomized control trial (n=374) showed music was associated with statistically significant effects in decreasing pain, including acute, procedural, chronic, and cancer pain ($p<0.00001$) (Lee, 2016). Though no studies have looked at the relationship between music and pain during IUD insertion specifically, studies have been done regarding similar procedures, such as colposcopy and manual vacuum aspiration. A metaanalysis of 5 randomized control trials

assessing the effect of music therapy showed no difference in anxiety levels (n=763, p=0.4) or pain (n=649) during (p=0.31) and after (p=0.33) colposcopy. (Abdelhakim, 2019). Similarly, a randomized control trial of 101 women randomized to undergo abortion with routine pain control measures only (ibuprofen and paracervical block) or with the addition of intraoperative music via headphones showed that intraoperative music, in fact, increased reported pain (p=0.045) (Guerrero, 2012). Due to these conflicting reports, our study aims to explore music therapy as a pain management strategy during LARC insertion specifically.

1.3 Research Design and Methods

A. Research Procedures

This will be a randomized control trial conducted in the gynecology clinic inside Robert Wood Johnson University Hospital (RWJ) and the offices of Rutgers Medical Group Obstetrics and Gynecology (RMG). A family planning attending alone at RMG or accompanied by obstetrics and gynecology (Ob/Gyn) residents at RWJ will perform all IUD insertions during this study period. Patients scheduled for an IUD, either the Mirena® (levonorgestrel-releasing intrauterine system 52 mg) or Paragard® (intrauterine copper contraceptive), at both locations will be instructed to take ibuprofen 30 minutes prior to their procedure.

Enrollment will occur during all weekdays at both RWJ and RMG. Eligible women will be able to read and write in English. Exclusion criteria include contraindications to IUD placement: Active pelvic infection, pregnancy, known distortion of uterine cavity, Wilson's disease (Paragard® only), breast cancer (Mirena® only). Eligible women will be enrolled if they are willing to be randomized. Written consent will be obtained from each participant.

After the consent process is completed, the patients will complete a survey which includes their demographic information, if they are currently menstruating, and their pregnancy history while sitting in the waiting room. The patient will also complete a 10 point visual analog scale (VAS) to report her baseline pain and a State Trait Anxiety Inventory (STAI). Vital signs will be recorded with an automated machine.

Participants will then be randomized to routine pain control measures or routine pain control measures plus music. Randomization will be completed by the study staff, who will open sequentially numbered, sealed, opaque envelopes. Allocation will be in a 1:1 ratio. Routine pain control will include instructions to take ibuprofen 600 mg 30 minutes prior to the procedure. These instructions will be given to all participants. It will be noted whether patients actually take ibuprofen or not by the study staff. Patients randomized to receive music in addition to routine pain control measures, will listen to preselected classical music played on the PI phone. Patients will control the volume.

A study staff member will be present in the room throughout the duration of the procedure in addition to the physician performing the actual insertion of the IUD. This study staff member will complete a procedure information sheet including vitals, type of IUD inserted, and the VAS and STAI at several points of the procedure (immediately prior to the procedure, point of speculum insertion, point of tenaculum placement, point of IUD insertion, and 5 minutes post-procedure).

B. Data Points

Pain scores will be collected on the VAS; anxiety scores will be collected on the STAI.

C. Study Duration

Each subject will participate only once during their actual outpatient appointment for IUD insertion. The overall duration of this study will be until the prespecified sample size determined based on power calculation is reached. This is estimated to take approximately 1 to 2 years.

D. Endpoints

The primary endpoint is pain scores. The secondary endpoint is anxiety.

1.4 Preliminary Data

There is no preliminary data.

1.5 Sample Size Justification

The goal of this study was to find a change in the pain score that would be clinically relevant. A 2 point reduction in the 10 point VAS was deemed as clinically significant. To detect a difference of at least 2 points with at least 90% power, two sided alpha 0.05, and a standard deviation of 3, this study required at least 48 women per arm.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The intervention being tested is music. Patients will receive either routine pain control measures only (control group) or routine pain control measures and music (treatment group). Routine pain control will include instructions to take ibuprofen 600 mg 30 minutes prior to the procedure. These instructions will be given to all participants. It will be noted whether patients actually take ibuprofen or not by the study staff. Patients randomized to receive music in addition to routine pain control measures, will listen to preselected classical music played on the PI phone.

B. Dependent Variables or Outcome Measures

Pain is the primary outcome measure. Pain will be measured on the VAS. Anxiety is the secondary outcome measure. Anxiety will be measured on the STAI

1.7 Drugs/Devices/Biologics

This study will use two different IUDs which are both FDA approved for this indication: Mirena® (levonorgestrel-releasing intrauterine system 52 mg) or Paragard® (intrauterine copper contraceptive). These will be inserted into the uterus by a physician at bedside.

A. Drug/Device Accountability and Storage Methods

For both RWJ and RMG, the IUDs are stored and secured in the Ob/Gyn department in CAB building. At both locations, nursing staff is responsible for preparation of the IUD. At both locations, an Ob/Gyn Physician will be inserting the IUD.

1.8 Specimen Collection

A. Primary Specimen Collection

No specimens will be collected in this study.

- **Types of Specimens**: N/A
- **Annotation**: N/A
- **Transport**: N/A
- **Processing**: N/A
- **Storage**: N/A
- **Disposition**: N/A

B. Secondary Specimen Collection

No specimens will be collected in this study.

- **Types of Specimens**: N/A
- **Annotation**: N/A
- **Transport**: N/A
- **Storage**: N/A
- **Disposition**: N/A

1.9 Data Collection

A. Primary Data Collection

- **Location**: At both RWJ and RMG, data collection will take place within two main areas: the waiting room and the patient exam room.
- **Process of Data Collection**: In the waiting room, patients will complete the demographic survey. They will also complete, the VAS and STAI for their baseline pain and anxiety scores, respectively. If the patient wishes to complete any of these instruments in private, she will be led into an unoccupied patient exam room. In the exam room, the providers will complete the provider survey regarding the patient. The providers will also record vital signs, BMI, and other pertinent medical information. While in the exam room, at several points through the insertion the VAS and STAI will be administered.
- **Timing and Frequency**: The patient survey will be completed once by the patient while she is in the waiting room. The provider survey will be completed once by the provider while the patient is in the exam room. The VAS will be completed by the patient at several points: immediately prior to the procedure, point of speculum insertion, point of tenaculum placement, point of IUD insertion, and 5 minutes post-procedure. The STAI will be completed immediately prior to the procedure and 5 minutes post-procedure.
- **Procedures for Audio/Visual Recording**: There will be no audio or video recordings of the patients.
- **Study Instruments**: The patient survey will include demographic information including: age, ethnicity, preferred language, marital status, education level, history of smoking, history of alcohol use, current medications, allergies, date of last menstrual period, menstrual history, exercise habits, current pain level, current anxiety level, history of depression, music interests, prior medical procedures, prior medical complications, pregnancy history, delivery history, miscarriage history, previous pain management techniques, and preferred method of music listening. The provider survey includes heart rate, blood pressure, respiration rate, body mass index (BMI), type of IUD inserted, medical complications, prior contraceptive use, gravidity, parity. The VAS is a well known and accepted instrument for quantifying pain. It has been used previously to report pain during IUD insertion (Mody 2018). The STAI is also a well known and accepted instrument for quantifying anxiety. It, too, has also been used previously to report anxiety in several different circumstances (Kendall 1976).
- **Ethnographic Studies, Interviews, Or Observation**: N/A
- **Subject Identifiers**: N/A

B. Secondary Data Collection

No data of this type will be collected.

- **Type of Records**: N/A
- **Location**: N/A
- **Inclusion/Exclusion**: N/A
- **Data Abstraction Form(s):** N/A

1.10 Timetable/Schedule of Events

Once we start recruiting patients after the IRB is approved, we expect it will take one to two years to achieve our prespecified sample size. At this point, the study will be concluded and we will analyze the data.

2.0 Project Management

2.1 Research Staff and Qualifications

The principal investigator is Dr. Glenmarie Matthews. Dr. Glenmarie Matthews is part of the Ob/Gyn faculty at Rutgers Robert Wood Johnson Medical School. She is fellowship trained in advanced family planning and recently successfully established a Ryan Grant at RWJ. With new increased access to contraception through this funding, she has been able to set up a contraception clinic that offers LARCs to women. She now seeks to reduce pain associated with IUD insertion in order to continue to make IUDs more acceptable and available to her patients. Dr. Amy Patel is an Ob/Gyn resident at Rutgers Robert Wood Johnson Medical School. She has been working with the population being studied as her patients over the past two years. Providing long term contraception to this population is of utmost importance to her. Along the same lines, she would like to reduce obstacles and negative perceptions the New Brunswick area population might have about LARCs. Dr. Cande Ananth is a biostatistician who has been and will continue to be involved in the study. He has completed power calculations to determine an appropriate sample size for this study. He will also be extensively involved in interpreting the results. Ryan Safarzadeh is a graduate student at Rutgers Graduate School of Biomedical Sciences. He is very interested in women's healthcare, including access to contraception.

2.2 Research Staff Training

Thus far, in designing this project, the research staff has been holding monthly meetings to discuss the research protocol. These meetings also serve to identify upcoming goals, concerns, and questions. These meetings will continue and will function to disseminate information regarding the research procedures and the duties and functions of each study staff member. Dr. Glenmarie Matthews will be present during all IUD insertions at RMG and RWJ and will serve to oversee and standardize all recruitment, consent, and date collections activities.

2.3 Resources Available

The majority of the resources required for any IUD insertion are those that are part of routine care. The only additional resources required are those related to the study intervention. In order to play music, this study requires a headset, which will be plugged into Dr. Glenmarie Matthews's phone, which is a HIPAA compliant phone provided by RWJMS. This headset will be completely funded by the study investigators. The study intervention is anticipated to cause no medical or psychological harm to the patient.

2.4 Research Sites

Gynecology clinic inside Robert Wood Johnson University Hospital (RWJ) and the offices of Rutgers Medical Group Obstetrics and Gynecology (RMG). There are no international research sites.

3.0 Multi-Center Research

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

All women with an appointment for IUD placement at RMG or RWJ who are able to read and write in English will be considered eligible for the study.

B. Recruitment Details

All eligible patients will be approached by a member of the study staff while they are sitting in the waiting room prior to their IUD insertion appointment. Each individual patient will be taken to an unoccupied patient examination room where, after briefly describing the study, the study staff will ask each eligible patient if she is willing to participate. No additional materials will be used to accomplish the recruitment efforts.

C. Subject Screening

The study staff member will review inclusion and exclusion criteria for all eligible women prior to consenting them to participate in an otherwise unoccupied patient examination room.

- **Inclusion Criteria**

  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.

- **Exclusion Criteria**

Exclusion criteria included contraindications to IUD placement: Active pelvic infection, pregnancy, known distortion of uterine cavity, Wilson's disease (Paragard® only), breast cancer (Mirena® only)

4.2 Secondary Subjects

There are no secondary subjects.

4.3 Number of Subjects

A. Total Number of Subjects

A total of 48 women per arm, or 96 total subjects are necessary to complete this project. We expect that approximately 200 women will need to be screened to successfully enroll 96 subjects.

B. Total Number of Subjects If Multicenter Study

N/A

C. Feasibility

In an average month, 20 women are seen for IUD insertion between both sites (RMG and RWJ). As the study intervention (music) confers no additional risk to routine management during IUD insertion, we anticipate that at least half of these women will consent to participate in the study. If approximately 10 women are enrolled in the study monthly, then we believe it is feasible to complete this study in little over a year.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**

  The consent process will take place in private in an otherwise unoccupied patient examination room of either RMG or RWJ prior to the patient's appointment.

- **Ongoing Consent**

  Ongoing consent is not required as the patient will only participate in the study for the duration of their appointment.

- **Individual Roles for Researchers Involved in Consent**

  Dr. Amy Patel, Dr. Glenmarie Matthews, and Ryan Safarzadeh will all be responsible for approaching/recruiting patients, discussing the study, determining inclusion and exclusion criteria, and subsequently consenting patients desiring to participate.

- **Consent Discussion Duration**
  The consent discussion is anticipated to take five to ten minutes with additional time devoted as necessary to answer any and all questions from a potential subject.
- **Coercion or Undue Influence**
  Prior to the conclusion of the consent process, all potential subjects will be reminded that participation in the study is purely voluntary and their refusal to participate will not impact their access to or the quality of care.
- **Subject Understanding**
  The teachback method will be utilized so that patients will restate everything explained to them in their own words to ensure that they comprehend the key study elements. There will be several opportunities for the patients to ask questions throughout the consent discussion.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
  N/A
- **Destruction of Identifiers**
  N/A
- **Use of Deception/Concealment**
  This research plan does not involve deception or concealment.
  a. **Minimal Risk Justification**
     N/A
  b. **Alternatives**
     N/A
  c. **Subject Debriefing**
     N/A

C. Documentation of Consent

- **Documenting Consent**
  Both the study staff member obtaining consent and the patient electing to participate in the study will sign and date the consent document. The participants will be provided with a copy of the consent document to retain for their records.
- **Waiver of Documentation Of Consent (i.e., will not obtain subject's signature)**
  We will be obtaining signatures from all participants.

4.5 Special Consent/Populations

A. Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
  N/A
- **Non-Parental Permission**
  Non-parental permission will not be obtained.
- **Assent Process**
  N/A
- **Documentation of Assent**
  N/A
- **Reaching Age of Majority During Study**
  N/A

B. Wards of the State

N/A

- **Research Outside of NJ Involving Minors**
  N/A

C. Non-English-Speaking Subjects
Patients able to read and write in Spanish will be included in this study.

- **Process for Non-English-Speaking Subjects**
  A study staff member certified in Spanish interpretation will obtain consent from all patients who are able to read and write in only Spanish and not English. A Spanish consent form will be used for these patients.
- **Short Form Consent for Non-English Speakers**
  N/A

D. Adults Unable to Consent / Decisionally Impaired Adults
Decisionally Impaired adults will not be recruited to participate in this study.

- **NJ Law-Assessment of Regaining the Capacity to Consent**
  N/A
- **Capacity to Consent**
  N/A
  a. **NJ Law-Selecting A Witness**
     N/A
  b. **Removing a Subject**
     N/A

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses
There will be no monetary cost to the patient for participating in the research.

B. Compensation/Incentives
There will be no monetary compensation or incentives provided to the patient for participating in the research.

C. Compensation Documentation
N/A

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
  Patients who participate in the study will almost certainly have a longer visit. Between the consent process and the patient survey that participants will need to complete, it is estimated that approximately 20 minutes will be added on to the patient's appointment. Other than this loss of time, there are no other inconveniences or harms that are foreseeable. The study intervention of music is not associated with any know harm.
- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  N/A.
- **Other Foreseeable Risks of Harm**
  There are minimal risks associated with possible loss of confidentiality. However, since patients will be signing the consent form with their names, a potential risk of breach of confidentiality does exist.
- **Observation and Sensitive Information**
  N/A.

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
Pregnancy is an exclusion criteria.

C. Risks of Harm to Non-Subjects
Non-subjects will not be involved in this research in any capacity.

D. Assessment of Social Behavior Considerations
N/A

E. Minimizing Risks of Harm
The only harm of this study is the inconvenience of dedicating additional time to the patient visit. This will be minimized as much as possible by including the consent process during the time the patient is waiting prior to her appointment. All data sheets will be kept locked in the Dr. Glenmarie Matthews' office. All electronic data will be stored in an encrypted hospital computer.

- **Certificate of Confidentiality**
  N/A.
- **Provisions to Protect the Privacy Interests of Subjects**
  The only people the participants will be providing information regarding the research to will be the study staff members and the physician and nurse assigned to her for the visit. This will serve to limit the number of people the participant interacts with or provides personal information to about the research. In subsequent appointments, their participation in the research will not be referenced unless the conversation is initiated by the former participant.

F. Potential Benefits to Subjects
Music has been previously shown to reduce pain and anxiety related to procedures as well as related to chronic diagnoses. This study seeks to determine is music has this effect during IUD insertion, as well. Patients who take part in this research and are randomized to the intervention group are anticipated to experience a decrease in pain and anxiety during their IUD insertion. We anticipate that this effect will last for the duration of the procedure and that it will reduce pain and anxiety by approximately 25%.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)
N/A

5.2 Family Educational Rights and Privacy Act (FERPA)
N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)
There will by no vulnerable populations involved.

A. Special Populations

5.4 General Data Protection Regulation (GDPR)
N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)
N/A

6.0 Data Management Plan

6.1 Data Analysis
Power analysis was completed to determine the sample size to be collected for each arm.
The results will be analyzed using t-tests and its nonparametric equivalent to determine if there is a difference in pain and anxiety scores between the two arms.

6.2 Data Security

All forms completed during the patient encounter (consent form, patient survey, provider survey, VAS, STAI) will immediately be locked in Dr. Glenmarie Matthews's office. Once this data is transcribed into electronic form, the paper forms will be discarded in HIPAA compliant bins. The electronic data will be stored on an encrypted hospital computer. No identifying data will be collected.

6.3 Data and Safety Monitoring

This research poses only minimal risk to the patient.

A. Data/Safety Monitoring Plan

N/A

B. Data/Safety Monitoring Board Details

N/A

6.4 Reporting Results

A. Individual Subjects' Results

The results of the study will not be shared with the subjects.

B. Aggregate Results

Aggregate study results will not be shared with subjects.

C. Professional Reporting

The results of this research are intended to be published in order to be shared with the scientific community.

D. Clinical Trials Registration, Results Reporting and Consent Posting

N/A

6.5 Secondary Use of the Data

There are no plans for secondary use of the data.

7.0 Research Repositories – Specimens and/or Data

The data collected in the course of this research will not be stored for future research. No specimens will be collected.

8.0 Approvals/Authorizations

A letter of cooperation from Robert Wood Johnson University Hospital will be obtained prior to commencing research at RWJ.

9.0 Bibliography

References

Abdelhakim, A. M., Samy, A., Abbas, A.M. (2019). Effect of music in reducing patient anxiety during colposcopy: A systematic review and meta-analysis of randomized controlled trials. *Journal of Gynecology Obstetrics and Human Reproduction*. doi:10.1016/j.jogoh.2019.07.007.

ACOG. (2017). Practice Bulletin No. 186: Long-Acting Reversible Contraception: Implants and Intrauterine Devices. *Obstetrics & Gynecology, 130*(5), 251-269. doi:10.1097/AOG.0000000000002400

Akers, A. Y. M., MPH; Steinway, Caren MSW, MPH; Sonalkar, Sarita MD; Perriera, Lisa K. MD, MPH; Schreiber, Courtney MD, MPH; Harding, Jennifer MPA; Garcia-Espana, J. Felipe PhD. (2017).

Reducing Pain During Intrauterine Device Insertion: A Randomized Controlled Trial in Adolescents and Young Women. *Obstetrics & Gynecology, 130*(4), 795-802. doi:10.1097/AOG.0000000000002242

Callahan, D. G. G., Laura F. Harney, Kathleen F. DiVasta, Amy D. (2019). Will it hurt? The intrauterine device (IUD) insertion experience and long-term IUD acceptability among adolescents and young women. *Journal of Pediatric and Adolescent Gynecology*. doi:doi: 10.1016/j.jpag.2019.0

Chor, J. B.-W., Julia. Golobof, Alex. Harwood, Bryna. Cowett, Allison. (2012). Ibuprofen prophylaxis for levonorgestrel-releasing intrauterine system insertion: a randomized controlled trial. *Contraception, 85*(6), 558-562. doi:doi: 10.1016/j.contraception.2011.10.015

Guerrero, J. M., Castaño, Paula M., Schmidt, Elizabeth O., Rosario, Linette, Westhoff, Carolyn L. (2012). Music as an auxiliary analgesic during first trimester surgical abortion: a randomized controlled trial. *Contraception, 86*(2), 157-162.

Kendall PC, Finch AJ Jr, Auerbach SM, Hooke JF, Mikulka PJ. The State-Trait Anxiety Inventory: a systematic evaluation. *J Consult Clin Psychol*. 1976;44(3):406–412. doi:10.1037//0022-006x.44.3.406

Lee, J. H. (2016). The Effects of Music on Pain: A Meta-Analysis. *Journal of Music Therapy, 53*(4), 430-477. doi:10.1093/jmt/thw012

Mody SK, Farala JP, Jimenez B, Nishikawa M, Ngo LL. Paracervical Block for Intrauterine Device Placement Among Nulliparous Women: A Randomized Controlled Trial. *Obstet Gynecol*. 2018;132(3):575–582. doi:10.1097/AOG.0000000000002790