Project Title: The use of lavender aromatherapy to decrease women's anxiety and perception of pain during office hysteroscopy

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Protocol

1. **Project Title:** The use of lavender aromatherapy to decrease women's anxiety and perception of pain during office hysteroscopy

2. **Investigators:**

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3. **Abstract:** Office hysteroscopy is an invaluable practice used to treat a myriad of gynecological processes in an outpatient setting[14]. This is a minimally invasive procedure that aids in the diagnosis and treatment of uterine and cervical pathology such as endometrial polyps, malignancy, uterine septum, or submucosal myomas[14]. Benefits of an outpatient procedure include decreased costs to the patient, avoidance of general anesthesia, and faster recovery times. However, a significant limiting factor is the perceived pain and anxiety associated with office hysteroscopy. Studies have shown that an increasing state of anxiety is often associated with high levels of pain perception and a high anxiety level can exacerbate pain[15, 17]. Lavender aromatherapy has been associated with decreased anxiety in a variety of clinical situations, including urodynamics[18] and during hemodialysis[11, 19]. In a randomized study of healthy controls, treatment with lavender aromatherapy will significantly decrease the pain intensity associated with Office Hysteroscopy and stress/anxiety levels as measured on a visual analog scale when compared to control subjects receiving distilled water placebo. The purpose of this study is to determine a difference in patient-reported anxiety and pain levels before, during, and after office hysteroscopy in patients given lavender aromatherapy versus placebo. The goal of this study is to find methods to decrease anxiety and perceived pain to help facilitate more office hysteroscopy procedures as opposed to proceeding to the Operative Room.

4. **Background:** Office hysteroscopy is an invaluable practice used to treat a myriad of gynecological processes in an outpatient setting[14]. This is a minimally invasive procedure that aids in the diagnosis and treatment of uterine and cervical pathology such as endometrial polyps, hyperplasia, malignancy, uterine synechia, uterine septum, or submucosal myomas[14]. Benefits of an outpatient procedure include decreased costs to the patient, avoidance of general anesthesia, and faster recovery times. However, a significant limiting factor is the perceived pain and anxiety associated with office hysteroscopy. Many women experience anxiety around the procedure which can affect overall patient satisfaction. Studies have shown that an increasing state of anxiety is often associated with high levels of pain perception and a high anxiety level can exacerbate pain[15, 17]. Strategies that have been implemented to help reduce anxiety include

patient education, interaction during the procedure, communicating through traditional or multimedia approaches, and music listening[16].

Lavender aromatherapy has been associated with decreased anxiety in a variety of clinical situations, including urodynamics[18], percutaneous coronary intervention in an intensive care unit[6], preoperative patients[7, 8,] during facial cosmetic injections[9], pre-procedural for colonoscopy or esophagogastroduodenoscopy[10] and during hemodialysis[11]. Ozel and colleagues found that the use of lavender essential oil aromatherapy for urodynamic testing reduced anxiety in patients[18]. There was a decrease in anxiety from baseline to catheter placement and 15 minutes post-procedure were greater in the lavender group compared to the control group[18]. In this randomized study of healthy controls, treatment with lavender aromatherapy will significantly decrease the pain intensity associated with Office Hysteroscopy and stress/anxiety levels as measured on a visual analog scale when compared to control subjects receiving a distilled water placebo. The purpose of this study is to determine a difference in patient-reported anxiety and pain levels before, during, and after office hysteroscopy in patients given lavender aromatherapy versus placebo. Providing more opportunities for office hysteroscopy can decrease the need to perform the procedure in the Operating Room and reduce costs and patient exposure to Anesthesia. Managing anxiety and perception of pain can help improve patient experiences and increase the utility of office hysteroscopy.

5. **Specific Aims:** The purpose of this study is to determine a difference in patient-reported anxiety and pain levels before, during, and after office hysteroscopy in patients given lavender aromatherapy versus placebo.

6. **Research Plan:** This study design is a randomized placebo control pilot trial. Women scheduled for office hysteroscopy at the UF Shands Women's Health Clinic (Medical Plaza/Springhill) will be invited to participate. For this pilot study, we will approach 40 participants to account for 25% dropout rate and we will aim to enroll 30 participants with 15 participants in the lavender group and the placebo group, respectively. Participants who meet inclusion criteria will be randomized to the aromatherapy or the placebo group after informed consent is obtained (from PI or co-investigators) and before undergoing the hysteroscopy procedure. Randomization will occur via the sealed envelope system. Participants will be given a randomly generated treatment allocation concealed within an opaque envelope. Aside from randomization to aromatherapy versus placebo, no procedures will be performed for study purposes that would not be normally performed in the clinical evaluation. Prior to starting the procedure, the clinic nurse will prepare the aromatherapy versus distilled water on a paper towel by applying two drops of each solution on a paper towel. The patients will hold the paper towel over their nose and then they will be asked to take two deep breaths. Before the physician comes in, the nurse will ask the participant to take a deep breath while holding the towel 3 inches from her face and will instruct the participant to continue to take normal breaths subsequently. It will not be possible to blind the participants or the examiner to the assigned group since the lavender oil will have a different scent than the placebo. However, the use of distilled water on the towel will allow the possibility that the deep breathing accompanying the instruction may have an effect on

reported pain and anxiety. We will be using lavender (Lavandula angustifolia, Aura Cacia) essential oil and distilled water for the study and placebo arms, respectively. The oil is 100% pure essential oil obtained from steam distillation of fresh flowering tops and tested for purity by gas chromatography/mass spectrometry, specific gravity, optical rotation, and refractive index. The PI will incur a minor cost of $13.29 associated with purchasing the lavender aromatherapy from Whole Foods Market.

Vaginoscopy approach will be utilized to perform the procedure. This avoids the use of a speculum in the vagina or tenaculum to grasp the cervix. This atraumatic technique reduces pain stimuli generated from the cervix and the vagina when using manipulating instruments. Vaginoscopy relies on hydrodilation of the cervical canal for entry of a miniaturized scope. This technique involves distending the vaginal vault with normal saline and advancing the scope to the posterior fornix. Gently pulling back until the external cervical os is visualized and then the scope is advanced into the cervical canal.

The participant will undergo the standard clinic exam in a standardized order. The participants will complete the Hospital Anxiety and Depression Survey (HADS) at baseline. The HADS is a reliable instrument for detecting states of depression and anxiety in the setting of a hospital medical outpatient clinic[26, 27]. This will be used to establish their baseline anxiety levels. Participants will then be asked to rate their level of anxiety and pain immediately before beginning the exam, immediately after catheter placement, and 15 min after termination of the study using a 10-point visual analog scale and the Wong-Baker pain scale[28]. At the end, the participants will also be asked to rate their satisfaction with the visit overall on a visual analog scale. Our primary objective is to determine the change in anxiety scores on the visual analog scale from baseline to immediate post-procedure.

- Inclusion Criteria:
  - Women aged 18 and over
  - Scheduled to undergo office hysteroscopy procedure
  - Able to give informed consent
  - Able to read and write in English
  - Anxiety score > 0 on a numerical scale at baseline

- Exclusion Criteria:
  - Any contraindication to office hysteroscopy (active pelvic infection, confirmed cervical or endometrial cancer severe hypertension, or any other condition that might be worsened by an uncomfortable test)
  - Allergy to lavender oil, or any of its components

- Withdrawal Criteria
  - The patient requests terminating participation

<u>Flow of Events:</u>

- The Principal Investigator or Co-Investigator will approach patients who are scheduled to undergo Office Hysteroscopy at each clinical site. PI (Resident Physician) and Co-Investigator (Attending Physician).

- Participants who agree to participate will be enrolled in the study and PI/Co-Investigator will conduct informed consent with the participant.

- Prior to starting the hysteroscopy procedure, the participants will complete a baseline questionnaire and a Hospital Anxiety and Depression Survey (HADS).
- Participants will be randomized into two groups (aromatherapy or placebo).
- Participants will hold a paper towel over their nose and take two deep breaths.
- For each group, the protocol will be the same except the towel held over the nose will be scented with lavender oil or distilled water.
- The hysteroscopy procedure will proceed under a standardized protocol that is not directly related to the study.
- Participants will be asked to rate their level of anxiety and pain immediately before, after, and 15 minutes after completing the procedure. Participants will be monitored for 30 minutes post-procedure and participation in the study will conclude at the end of this time interval.

7. **Possible Discomforts and Risks:** The risks and discomforts with this study are based on baseline risk/discomforts associated with the hysteroscopy procedure. Specifically related to the study, the risk involves exposure to Lavender oil and possible side effects associated with this exposure. We do not anticipate any significant complications associated with the procedure or the study oil. However, we will monitor the participant for at least 30 minutes post-procedure for side effects related to the oil, such as nausea, vomiting, headache, or allergic reaction. Women are given verbal and written post-op instructions by the clinic nurse upon discharge. Participants will be provided with the phone number of the clinic and PI and will be instructed to contact the clinic and/or PI should have any questions or problems.

   Additional risks include breach of confidentiality. To ensure the privacy of participant information, collected data will be stored on an electronic base encrypted database (Redcap) and this will only be accessible to study staff. Any additional research documents will be saved on a password-encrypted jump drive and locked in a filing cabinet in the Minimally Invasive Gynecologic Surgery office at the Springhill or Medical Plaza office. At the completion of the study, all personal identifiers will be destroyed in a HIPAA-compliant manner.

8. **Possible Benefits:** Participants may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. Information gathered from this study can help standardize hysteroscopy procedures by implementing potential stress relievers. The risks posed to participants are minor and very rare. The benefits of gaining more knowledge or how to adjust future patient care makes this study worthwhile. Participants

randomized to the aromatherapy treatment arm may benefit from perceived reduction in pain and anxiety associated with the hysteroscopy procedure.

9. **Conflict of Interest**: No conflict of interest associated with this study.

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