Study Title: Implementing a Paced Deep Breathing Module to Decrease Preoperative Anxiety in Gynecological Surgery Patients

This study aims to reduce preoperative anxiety in patients undergoing gynecological surgery by the implementation of a guided paced deep breathing module introduced into the preoperative setting. If this intervention is successful in reducing patient anxiety, we plan to implement into practice the guided paced deep breathing module that every patient is offered preoperatively.

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Each member of the study team is in compliance with Mayo Clinic Institutional Review Board Human Subjects Training. The study is supported by the staff on Eisenberg 1-4, the Doctor of Nurse Anesthesia Practice program faculty and staff in the Complementary and Integrative Medicine Program.

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Abstract

Preoperative anxiety is a common occurrence for many patients undergoing all types of surgery.[1,2] Patients with a high level of anxiety before surgery have been shown to have numerous negative outcomes both intra-operatively and post-operatively.[3-10] Many studies have shown that preoperative psychological interventions that aim to reduce anxiety also result in improved post-operative behavioral and clinical recovery.[8] Currently, the most common method to treat preoperative anxiety is the administration of a prescription benzodiazepine.[11] However, there is limited clinical evidence that supports the use of sedative premedication, such as with a benzodiazepine, before surgery.[12] Complementary integrative medical therapies including music, massage, guided imagery, and deep breathing have been proposed to minimize stress and pain in surgical patients.[13,14] These therapies are thought to be effective by evoking the relaxation response through stimulation of the parasympathetic nervous system and engagement of the patient in the healing process.[14] Relaxation and deep breathing, particularly, have been shown to reduce pain, anxiety, and "tension-anxiety" in hospitalized patients.[14,15] Based on this evidence, a guided paced deep breathing module has been proposed to reduce preoperative anxiety in patients undergoing gynecological surgery at Mayo Clinic Rochester Methodist Hospital. In this study, patients' anxiety will be assessed pre-intervention on a 0-10 numeric rating scale, as well as post-intervention and a paired t-test will be used to assess effectiveness. Additionally, qualitative questions will be administered via a questionnaire post-intervention to gain more insight on the effectiveness of the intervention. The feasibility of the intervention in the busy preoperative setting will be evaluated by assessing how many times a patient is interrupted while participating in the paced deep breathing module. If this module is found to be effective in reducing patients' anxiety, it will be implemented into practice so that every patient is offered the module preoperatively.

Research Plan

I. Background and Significance:

Pre-operative anxiety is a common occurrence for many patients undergoing all types of surgery. Fears concerning the anesthesia process, fear of death or being cut, of a poor prognosis, fear of pain and no access to pain medications after the surgical procedure combined with fear of the unknown and loss of control all contribute to excess preoperative anxiety.[1,2] Patients with high anxiety before surgery have been shown to have numerous negative outcomes both intra-operatively and post-operatively. These include increased doses of anesthesia induction agent required to achieve loss of consciousness,[3,4] increased post-operative pain scores[5,6] and analgesic use,[6] increased in-hospital mortality and major morbidity,[7] increased cost and length of stay,[8] increased rates of surgical site infections,[8] and decreased overall patient well-being and satisfaction.[9,10]

Many studies have shown that pre-operative psychological interventions that aim to reduce anxiety also result in improved post-operative behavioral and clinical recovery.[8] Currently, the most common method to treat preoperative anxiety is the administration of a prescription benzodiazepine. However, because of the temporary

effect of this medication and its side-effects, this method may not be the best treatment.[11] There is limited clinical evidence that supports the use of sedative premedication, such as with a benzodiazepine, before surgery.[12] In a well-designed randomized controlled trial, patients treated preoperatively with 2.5mg of lorazepam were shown to have a prolonged time to extubation and decreased rate of early cognitive recovery. Additionally, the study found that premedication with lorazepam did not improve patient satisfaction.[12]

Complementary integrative medical therapies including music, massage, guided imagery, and deep breathing have been proposed to minimize stress and pain in surgical patients.[13,14] These therapies are thought to be effective by evoking the relaxation response through stimulation of the parasympathetic nervous system and engagement of the patient in the healing process.[14] Relaxation and deep breathing, particularly, have been shown to reduce pain, anxiety, and "tension-anxiety" in hospitalized patients.[14,15]

Based on this evidence, an electronic paced deep breathing module has been proposed to reduce preoperative anxiety in patients undergoing gynecological surgery at Mayo Clinic Rochester Methodist Hospital. The gynecological surgery population has been selected because of research suggesting women tend to have a higher level of anxiety before surgery and may be more receptive to relaxation exercises.[16-18] Additionally, women undergoing gynecological surgery were found to have an average anxiety rating of four on a zero to ten numeric rating scale.[17]

II. Purpose of the Study:

The purpose of this study is to evaluate the effectiveness of an electronic guided paced deep breathing module implemented into the preoperative setting of gynecological surgery to reduce patient anxiety. If this intervention is found to be effective, we plan to implement into practice the paced deep breathing module that every patient is offered preoperatively.

III. Specific Aims of the Study:

Primary Aim: The study's primary aim is to assess if utilizing an electronic paced deep breathing module administered in the preoperative setting can decrease a patient's anxiety level prior to undergoing gynecological surgery. This study will determine if more research is needed or if the results are overwhelmingly positive in reducing anxiety, we plan to implement into practice the paced deep breathing module that every patient is offered preoperatively.

Secondary Aim: The secondary aim of this study is to collect qualitative data regarding patient satisfaction with the paced deep breathing module.

Tertiary Aim: The tertiary aim of this study is to evaluate the feasibility of implementing a paced deep breathing module into the busy preoperative setting of gynecological surgery.

Hypothesis: In adult females undergoing gynecological surgery, the use of a preoperative electronic guided paced deep breathing module will decrease anxiety levels.

IV. Literature Review:

The clinical practice question was used to guide the literature search. Preliminarily, PubMed was searched to determine if anxiety before surgery was, in fact, a problem. Key terms included perioperative period combined with anxiety or distress and outcomes or effects. Limitations included only articles that had been peer-reviewed and were available in English between January 1, 2005 and December 31, 2015. Next, the clinical practice question was searched using databases: CINAHL, Embase, PubMed and PsycINFO covering a period of the last ten years, 2005 to 2016. Key search terms included variations of preoperative period combined with breathing exercises or meditation or guided imagery and anxiety or distress. Limits were set to only include articles that had been peer-reviewed and were available in English. Additionally, National Guideline Clearinghouse, Cochrane Collaboration, Joanna Briggs Institute and the Anesthesia Patient Safety Foundation were searched for practice guidelines pertaining to the subject, but none existed. Of the articles reviewed, selections for included articles were made for relevance, availability, and application to the adult population. The reference lists of the selected articles were then reviewed for additional articles that were deemed important to be included. Additionally, expert opinion was sought for inclusion of articles pertaining particularly to complementary and integrative medicine modalities.

Through appraisal of this evidence commonalities were identified, along with similar research methods, and a predominant level of evidence emerged. A total of 21 articles regarding complementary and integrative therapies implemented to decrease anxiety in the hospital setting have been reviewed. Interventions varied from educational interventions, guided deep breathing exercises, guided imagery, music interventions, to massage, either individually or in combination with other therapies. Ten of the 21 articles specifically mentioned a guided breathing intervention.[13, 15, 18-25] Different modalities were utilized to deliver the interventions including audio CDs, pamphlets, instruction from providers, and iPads or iPods. Of the ten articles reviewed investigating a breathing intervention specifically, five included interventions that were administered before surgery[18,19,22,24,25] and the remaining offered therapies during procedures such as dressing changes,[15] chemotherapy,[13] gynecology exams,[20] hospitalization for stem cell transplant[21] and patients suffering from panic attacks.[23] Of the studies offering pre-operative interventions, they were offered approximately one day before surgery[18,19,22,24,25] and some continued post-operatively.[22,24] The types of surgery involved in the studies that offered a breathing intervention pre-operatively included trauma and orthopedic surgery[19,22] including joint replacements,[24] as well as coronary artery bypass grafting.[25]

Of the outcomes measured in the breathing intervention studies, the majority of studies included a primary outcome of anxiety,[15,18-25] or tension-anxiety[13] as well as

various secondary physiological outcomes such as systolic and diastolic blood pressure and heart rate[18,20,24.] Other secondary measures included pain,[15, 19,22,24,25] self-efficacy,[19] fatigue,[13] sleep satisfaction,[22] and depression.[21, 23] Scales used to measure the primary outcome of anxiety included Spielberger's State-Trait Anxiety Inventory-State Scale,[18,19,21,22,24] Visual Analog Scales,[15,24] the Beck Anxiety Inventory,[25] the Episodic Anxiety Scale[23] and numeric rating scales.[20]

Similar research methods were utilized in many of the articles. The majority of studies, nine of ten, were well-designed single or multi-site randomized controlled trials,[13,21,23-25] or quasi-experimental trials[15,18,19, 22] with a predominant Level of evidence at II or III. One Level IV study was found—a pilot study.[20]

While consulting the evidence, themes were identified supporting complementary and integrative therapies, especially guided deep breathing exercises, to reduce anxiety in the preoperative period. Of the ten studies that focused on guided breathing exercises specifically, nine found statistically significant reductions in anxiety.[13,15,18,19-23,25] Of the five studies also investigating changes in pain scores post-intervention, all but one found statistically significant reductions.[15,19,22,24] Additionally, of the three studies also measuring physiological changes in outcomes such as systolic and diastolic blood pressure, heart rate, and respiratory rate all three found positive statistically significant physiological improvements in the intervention group.[18,20,24] Statistically significant improvements were also seen in self-efficacy,[19] fatigue,[13] depression,[21,23] and sleep satisfaction[22] in the intervention groups.

Trends were seen supporting complementary integrative therapies such as guided deep breathing exercises to be effective in reducing anxiety in the preoperative period, but results didn't necessarily translate post-operatively. However, of the qualitative data that was collected, all comments and patient experiences were positive with no safety concerns that arose. Common themes were helpfulness of the intervention and induced relaxation the patient felt after the intervention. Additionally, gender effects emerged with women reporting higher levels of anxiety preoperatively than males and relaxation techniques having a more profound effect on women than men.[16,18]

Considering this evidence, the implementation of a paced deep breathing module in the preoperative period to reduce anxiety in women undergoing gynecological surgery is supported. Based on this literature review, the research team hypothesizes this intervention to be very effective in reducing patient anxiety. Paced deep breathing has been selected as the complementary therapy to reduce anxiety because of the overwhelmingly positive results that were seen while conducting this literature review. Ninety percent of the studies reviewed that looked specifically at guided breathing exercises to reduce anxiety in the hospital setting found statistically significant results. This intervention, additionally, has been found to be cost-effective and easy to implement. Furthermore, female patients undergoing gynecological surgery have been selected because of the gender effects observed in the literature.[16-18]

V. Theoretical Framework:

The theoretical model being used for this study is Herbert Benson's relaxation response. The relaxation response is defined as physiological changes that are provoked by assuming a relaxed position in a quiet environment, closing one's eyes, engaging in repetitive mental action and passively ignoring distracting thoughts.[26] The physiological changes associated with the relaxation response are consistent with decreased sympathetic nervous system activity and include decreased oxygen consumption, heart rate, arterial blood pressure, respiratory rate and arterial blood lactate.[26] Patients participating in the present study will be instructed to resume a relaxed position in a quiet, dimly-lit environment, close their eyes and focus their attention on the repetitive nature of their inhalation and exhalation. The goal is to invoke the relaxation response and lower preoperative anxiety to reduce negative outcomes that have been associated with high levels of anxiety going into surgery.

Additionally, the Neuman Systems Model can be applied. "The Neuman Systems Model is a systemic perspective of health and wellness, defined as the condition or the degree of system stability, that is, the condition in which all parts and subparts (variables) are in balance or harmony with the whole of the client/client system."[27, p.12] The model is based on the individual's continuous relationship to environmental stress factors. These environmental stress factors have the potential to cause a reaction or a symptomatic reaction to stress thus affecting the client's current health status.[27] This model relates to the present study in that the patient is being treated in a holistic manner on the basis that anxiety before surgery has negative outcomes both intra-operatively and post-operatively, thus preoperatively treating the patient's anxiety with the deep breathing module will, in turn, positively benefit the patient's health status.

VI. Significance:

Guided deep breathing has been found to be effective in reducing patient anxiety in the hospital setting, including during the preoperative period. However, this will be the first study to implement a guided deep breathing focused intervention into the *immediate* preoperative period for gynecological surgery patients to determine its effectiveness on reducing anxiety and evaluate patient satisfaction. Currently, gynecological surgery does not offer any such intervention. This will be the first approach to reduce patients' preoperative anxiety with a deep breathing intervention. This study has the potential to significantly add to the evidence and literature supporting the potential benefits of paced deep breathing exercises in the immediate preoperative setting. It will also provide a baseline for continued research on the benefits of paced deep breathing utilized in the immediate preoperative setting in specialty practices other than gynecological surgery.

VII. Methods:

This is a study with a pre- and post-test quasi-experimental design. This study will specifically examine an electronic paced deep breathing module for adult female patients undergoing gynecological surgery in the preoperative setting. This pre/post-test design was chosen to measure the primary outcome of anxiety level and gain patient's feedback on the module, as well as evaluate the feasibility of implementing the module into the busy preoperative setting of gynecological surgery.

a. Subjects and setting:

The study will be offered to a convenience sample of 45 adult female patients in the preoperative area of gynecological surgery on Eisenberg 1-4 at Mayo Clinic Rochester Methodist Hospital. This unit has approximately ten private rooms where patients are called from the outpatient AM admit area or hospital room to be evaluated and wait until called into the operating room for surgery. All patients undergoing gynecological surgery pass through this unit. According to nurses working on Eisenberg 1-4, the average length of stay in these rooms is about one hour.

All patients recruited will be assigned to the intervention group, as there is no control group. The sample size for this investigation was determined for the primary outcome of anxiety assessed pre- and post-intervention. From previous investigations which have assessed interventions aimed at reducing anxiety in surgical patients, the magnitude of the effect (i.e. change in anxiety expressed in SD units), has ranged from 0.5 to 0.9.[18,19] In general, for a one-sample study a sample-size of N=45 will provide statistical power (two-tailed, alpha=0.05) of 90% to detect a change of 0.5 SD. Therefore a sample-size of N=45 is proposed.

Inclusion Criteria: Women aged 18 years or older undergoing gynecological surgery on Eisenberg 1-4; English-speaking; Able to complete pre- and post-intervention questionnaires; Able to read and understand informed consent form

Exclusion Criteria: Non-English speaking women; first-case of the day gynecological surgery patients

b. Instruments and Data Collection (See Appendix):

1. Rapid Anxiety Assessment Tool (RAAT) 0-10 numeric rating scale
2. Qualitative questions regarding paced deep breathing module
3. Demographic data collected on pre-intervention survey

Baseline anxiety will be assessed upon admission to Eisenberg 1-4 using the Rapid Anxiety Assessment Tool (RAAT) zero to ten numeric rating scale and demographic information will be collected. This tool has been validated in the literature and is a single-item numeric rating scale that provides a quick assessment of patients' anxiety level.[17] The tool rates anxiety on a zero (no anxiety) to ten (worst anxiety possible) numeric scale and is easy for patients to use.[17] The tool additionally has been correlated with Spielberger's State-Trait

Anxiety Inventory-State Scale with r=0.77 validity in a sample of 197 patients evaluated in the preoperative period.[17]

Demographic data for the study population will be collected on the pre-intervention questionnaire including age, diagnosis, type of surgery, and whether the patient has utilized deep breathing or meditation exercises within the last twelve months. After the intervention, anxiety will be assessed again using the RAAT numeric rating scale and qualitative questions regarding the module will be assessed. Data will be collected from paper questionnaires.

Feasibility will be assessed by determining if and how many times each patient was interrupted while using the paced deep breathing module.

c. Procedures:

Patients will be recruited by primary investigators, Natalie Laska, RN, SRNA, and Dr. Susanne Cutshall, APRN, CNS, D.N.P., as well as co-investigator, Heather Ondler Hinson, by the assistance of a research flyer (see appendix). Additionally, a surgical listing of patients undergoing gynecological surgery for each day will be obtained by the primary investigators or co-investogator. Inclusion/exclusion criteria will be evaluated to determine eligibility and eligible patients will be approached by the primary investigators/co-investigator and asked if one is interested in participating in a deep breathing/meditation intervention. The primary investigators/co-investigator will then provide information and instruction regarding the questionnaires and intervention module to the patient. The patient will then be asked for verbal consent and written signed HIPAA authorization to participate. Once consent is obtained, the primary investigators/co-investigator will provide the patient with the questionnaire packet (including pre- and post-intervention questionnaires) as well as introduce and set up the module on an iPad or portable laptop for the patient. The paced deep breathing module consists of ten minutes of a guided breathing exercise while culminating a calm and energized mind. It was developed by Dr. Amit Sood, M.D. and is entitled "Calm and Energize: A Meditation with Your Breath." The script for this meditation is led by Dr. Sood and is as follows:

> "Calm and energize, a meditation with your breath. Let us settle ourselves in a quiet, safe and comfortable place. Start your practice by welcoming this lovely hibiscus that is slowly waking up to the world. Notice the five overlapping petals. Notice their color—the shallow wrinkles on their surface and folded frilly edges (video of hibiscus flower opening is shown). Like this flower, imagine you have opened your heart to invite hope and possibilities into your life. When you're ready, gently close your eyes making sure your eyelids are only lightly touching each other. Now, gradually shift your attention to the rhythm of your breath. Observe the flow of your breath without trying to change it in any way. Notice the subtle sensation of air flow under your nostrils as you breathe in fresh, cool air and breathe out air that is warmed by your lungs. Next, we will synchronize our breath to the two flute sounds. This is the sound for breathing in (pause for flute sound) and this is the sound for breathing out (pause for flute sound). Begin slow deep breathing synchronizing your

breath to the two flute sounds. Inhale (flute), exhale (flute), inhale (flute), exhale (flute), inhale (flute), exhale (flute). Make sure your eyes are relaxed with your eyelids only lightly touching each other and your face has a gentle smile. Now we will calm and energize our heart. Follow your breath from the tip of your nose to the deepest place in your heart. While breathing in, imagine your heart is recharging with calming, soothing energy. While breathing out, imagine your fatigue and hurt are all melting away. Inhale (flute), exhale (flute), inhale (flute), exhale (flute), inhale (flute), exhale (flute continues without instruction). Make sure your eyes are relaxed with your eyelids only lightly touching each other and your face has a gentle smile. Now, we will calm and energize our eyes. Follow your breath from the depth of your heart to both of your eyes. While breathing in, imagine your eyes are recharging with calming, soothing energy. While breathing out, imagine all the fatigue in your eyes is melting away. Inhale (flute), exhale (flute), inhale (flute), exhale (flute), inhale (flute), exhale (flute continues without instruction). Make sure your eyes are relaxed with your eyelids only lightly touching each other and your face has a gentle smile. Now, we will calm and energize our brain. Follow your breath from the depth of your heart to the farthest places in your brain. While breathing in, imagine your brain is recharging with calming, soothing energy. While breathing out, imagine all the fatigue in your brain is melting away. Inhale (flute), exhale (flute), inhale (flute), exhale (flute), inhale (flute), exhale (flute continues without instruction). Make sure your eyes are relaxed with your eyelids only lightly touching each other and your face has a gentle smile (flute continues). Now, think about one person you know who truly cares about you. Bring that person's face in front of your eyes, and then send that person your silent gratitude. Imagine that person is being protected for the week with the energy you just sent. We will now transition out of the meditation practice. Give yourself a nice stretch, set a positive intention for the rest of the day, and then when you're ready you can open your eyes. I hope you have a wonderful day."

During this time, the patient will be left alone with the door shut and lights dimmed. Family present in the room will be welcome to stay. A door card will be placed outside the room to minimize interruptions during this time. At the completion of the module, a second anxiety score using the RAAT numeric rating scale will be collected and a short questionnaire will be completed (see appendix). A nurse on Eisenberg 1-4 will collect the completed questionnaire packet from each participating patient, to reduce bias, and bring to the primary investigators/co-investigator for secure filing. Information as to whether the patient received a benzodiazepine in the preoperative setting will be collected from the patient's medication administration record. Prior to the implementation of the study, nurses on Eisenberg 1-4 will be introduced to the intervention module and have the study explained. Julie Somheil, the nurse manager of the unit, has already shown support of the study and informed nurses on the unit

about it. While observing on this unit, primary investigators have already received support and positive feedback regarding the study from many nurses.

Natalie Laska, RN, SRNA along with Dr. Susanne Cutshall, APRN, CNS, D.N.P. or Heather Ondler Hinson will be approaching patients individually and consenting them to participate in the study the day of surgery, as well as explain the module and questionnaires to patients and deliver the questionnaire packet. Nurses on EI 1-4 will collect the completed questionnaire packets and bring them to primary investigators/co-investigator. All study materials will be kept in a secured file by the primary investigators/co-investigator. Data analysis will be performed by Natalie Laska, RN, SRNA, with assistance from the statistician, Darrell Schroeder.

The only potential risk factor foreseen is emotional harm by feeling distressed from answering the questionnaires. If a patient chooses not to participate or end participation early, his or her care will not be compromised.

d. Data Analysis:

Subject characteristics will be summarized using mean±SD for continuous variables and frequency counts and percentages for categorical variables. The primary outcome for this study will be anxiety which will be assessed pre- and post-intervention using RAAT (0-10 numeric rating scale). The change from pre- to post-intervention will be assessed using the paired t-test (or signed rank test). Results from the short post-intervention survey will be summarized using methods appropriate for qualitative data collection including content analysis dividing responses into meaning units, condensing these and interpreting the underlying meaning to identify sub-themes and themes.[28]

e. Limitations:

- This is a study with no control group using a convenience sample
- Small sample size
- Limited generalizability

VIII. Human Subjects Consideration:

a. Potential Risks:

The potential risks of this research study are minimal. In previous studies utilizing deep breathing practices, no side effects were observed. There is no compromise to present or future care if the patients refuse the offer of the paced deep breathing intervention or if the intervention is stopped early. Patients will be given the option to stop the intervention at any time if they have concerns or feel uncomfortable.

b. Protection:

We will adhere to HIPAA regulations and protect the privacy and confidentiality of the patients involved from recruitment, intervention, and analysis of data. If at any time a participating patient exhibits signs of distress, the subject will then be given the choice to either continue or discontinue with the paced deep breathing intervention. All study participants will be given a unique ID code separate from their MC number and all data will be kept in a secured file and secure electronic server.

c. Gender/minority Mix:

English as the primary language is a necessity for this small sample size study due to the nature of excluding the need for an interpreter to interpret the pre- and post-intervention questionnaires.

IX. Appendix

a. Timeline:

i. Complete nursing research ancillary committee review- July 2016
ii. Turn in to IRB- August 2016
iii. Start study- when primary investigators are available- March 2017
iv. Complete study by end of May 2017
v. Review study results and surveys- June-September 2017
vi. Begin writing results of study for publication- October 2017-January 2018
vii. Dissemination of results via oral and poster presentations-Spring/Fall 2018
viii. Apply for publication- Winter 2018/2019

b. Budget:

No budget is needed for this project. No monies are currently being requested for statistical support or data entry. Data will be abstracted and entered into spreadsheets/Redcap by co-investigators. The Center for Clinical and Translational Science (CCaTS) Research Resources will assist with the statistical analysis. An iPad will be rented through media support services. A poster will be generated to disseminate results. Per institutional guidelines for poster development and preparation, Media Support Services will provide support and print the poster at no charge.

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