A Quality Improvement Project on Anxiety Management Before Ketamine-Assisted Psychotherapy

Kiera Paulo  
*University of San Francisco, ktpaulo1@yahoo.com*

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A Quality Improvement Project on Anxiety Management Before Ketamine-Assisted Psychotherapy

Kiera Paulo

University of San Francisco, School of Nursing and Health Professions

N789 DNP Project

October 15, 2023

Dr. Trinette Radasa
Abstract

Background: This Quality Improvement project sought to determine if a brief progressive muscle relaxation (PMR) session could decrease patient anxiety before receiving intramuscular (IM) injections for ketamine-assisted therapy. Problem: The Kerstin Helgason, NP clinic does ketamine-assisted therapy, and many patients express anxiety beforehand, either due to a fear of needles or nerves surrounding the medication treatment. Intervention: This project implemented a brief progressive muscle relaxation therapy for patients with anxiety before receiving their IM injection. Measures: The patient’s anxiety levels were measured before and after the PMR therapy using a five-point Likert scale ranging from none to very severe. Results: The data was analyzed using both paired t-tests and the Wilcoxon signed-rank tests and both found that there was a significant difference between pre- and post-anxiety levels. Conclusions: Utilizing brief progressive muscle relaxation sessions decreases anxiety in patients receiving IM ketamine-assisted therapy injections. Dissemination: The following are to expand research of brief PMR into other procedural areas and research into its effects on blood pressure and the psychedelic journey.

Keywords: pre-procedure, anxiety, mindfulness, progressive muscle relaxation
Problem Description

Fear of needles affects as much as 25% of adults (Shmerling, 2021). This fear can range from an annoyance to a phobia – called trypanophobia (Shmerling, 2021). Even if individuals do not fear needles, they may be anxious about the medication being given via IM injection. Pre-procedural anxiety may not cause people to avoid medical care, but even if they can control the fear, it can still fill them with dread (NHS Staff, 2018). Anxiety can lead to physical stress responses that result in increased blood pressure, increased heart rate, increased rate of breathing, decreased depth of breathing, and muscle tension (Rose et al., 2023). Other physical stress response symptoms include heart palpitations, excessive sweating, loss of appetite, dry mouth, nausea, and shaking (NHS Staff, 2018). Emotional symptoms that stem from anxiety include irritability, panic, detachment, and poor concentration (NHS Staff, 2018).

The Kerstin Helgason NP clinic sees patients with various mental health disorders. One unique treatment they provide is IM injection ketamine-assisted therapy for treatment-resistant depression. Before the injection of ketamine, many patients have reported anxiety. The two main reasons this has been reported are fear of needles and nervousness around the procedure. Procedural anxiety can stem from the fact that the patient has never tried a psychedelic before or that they have previously had a poor experience with psychedelics. Regardless of the source of the patient’s anxiety, finding a quick, non-invasive way of helping the patient manage their immediate stress response can promote a more relaxed and calmer environment and prevent them from developing physical or emotional symptoms that overwhelm their ability to cope.
Available Knowledge

**PICO Question**

Compared to no brief mindfulness intervention, can a brief mindfulness intervention decrease pre-injection anxiety in patients receiving intramuscular ketamine-assisted therapy?

**Search Methodology**

A literature search was undertaken to find pertinent studies. Compiling relevant research on the subject was done through a systematic review of evidence on the Cumulative Index to Nursing and Allied Health Literature (CINAHL) Ultimate and APA PsychInfo databases. The keywords used to search for relevant articles were “PMR or progressive muscle relaxation” and “anxiety”. The search yielded 105 results. The search was then limited to English and published between 2013 and 2023. As a result, the number of articles decreased to 38. The search was again limited to Full-Text articles and Academic Journals only. The results produced 32 articles. Modifiers used to eliminate irrelevant articles were removing those unrelated to PMR to decrease anxiety, removing ones that contained information on long-term PMR interventions instead of short-term ones, and removing articles that did not address PRM as the intervention. These modifiers led to six articles that were relevant and useful to the development of this project. An evaluation table describing each of these articles can be found in Appendix J.

*Progressive Muscle Relaxation*
In 2015, Carver and O’Malley completed a pilot study to assess whether PMR could decrease anxiety in 15 nursing students doing clinical simulations. They had a control group that did not participate in the intervention and an experimental group that participated in a 10-minute prerecorded PMR audio session before their clinical simulation. Before and after completing the PMR, participants from both groups filled out the State Trait Anxiety Inventory (STAI) to measure their anxiety levels. The Shapiro–Wilk test was used to analyze the data and there was a statistically significant decrease for the experimental group compared to the control group in the STAI scores.

Nurjanah et al. completed a quasi-experimental non-equivalent control group design to determine what effect PMR has on 36 mothers scheduled for section cesarean. Patients completed the Zung Self-Report Anxiety Scale before and after a 20-minute PMR session (the experimental group) or a 20-minute deep breathing exercise (the control group). The independent paired t-test was used to analyze the data. They found that PMR techniques reduced anxiety in mothers facing section cesarean surgery.

In 2015, Charalambous et al. completed a randomized controlled trial to test the effectiveness of PMR and guided imagery (GI) in decreasing stress in 208 breast or prostate cancer patients undergoing chemotherapy. Over three weeks, patients completed supervised and unsupervised GI and PMR sessions. The patients completed the Zung Self-Rating Anxiety Scale and the Beck Depression Interview II to measure their anxiety and depression levels at baseline and the end of the three-week intervention period. Using a Student’s t-test to analyze the data, the study found that GI in combination
with PMR is more effective in reducing stress for patients with prostate or breast cancer undergoing chemotherapy than standard treatment alone.

Liu et al. (2022) completed a pilot study that assessed the impact of PMR combined with expressive arts therapy in 116 patients with gynecological malignancies needing surgery. Patients in the intervention group participated in three expressive arts therapy and PMR sessions. Both groups completed the Hospital Anxiety and Depression Scale (HADS), the State Anxiety Inventory (SAI), and the Hearth Hope Index (HHI) before the intervention and after the sessions. The intervention group also completed the SAI after each session. An independent samples t-test and a paired samples t-test were used to analyze the data. The study found that PMR combined with expressive arts therapy effectively reduced the patient’s immediate anxiety.

Park et al. completed a randomized controlled trial in 2018 to see if PMR therapy could relieve dental anxiety. Sixty-eight periodontal patients were placed in intervention and control groups. Those in the intervention group received PMR therapy for 20 minutes and both groups received oral health education for 15 minutes before periodontal treatment once weekly for four weeks. Four weeks and three months after the intervention, changes in patients’ depression symptoms, dental anxiety, heart rate, blood pressure, and salivary cortisol were measured. The data was analyzed using the Wilcoxon rank-sum test, the Fisher’s exact test, and the chi-square test. The study found that using PMR created a statistically significant reduction in dental anxiety scores compared to the control group at the four-week and three-month mark.
In 2016, Xie et al. conducted a randomized controlled clinical study to evaluate the impact of PMR on self-efficacy and state anxiety in hospitalized patients admitted for elective surgery on extremity fractures. Ninety patients were placed in either the control or the PMR group, in which patients received PMR therapy within 48 hours of being admitted and then twice a day until being discharged. All the patients completed Self-Efficacy Scales and State Anxiety Inventory (SAI) before and after the intervention was completed. The chi-square test was used to analyze the data and found that patients in the PMR therapy group had more improvement in state anxiety than those in the control group.

**Summary/Synthesis of the Evidence**

These studies support a consensus that there are benefits to using progressive muscle relaxation to decrease anxiety. Some articles used PMR combined with another relaxation technique or studied measurements other than anxiety levels. They all also varied on the time length of the PMR and whether it was a one-time session or a consistent number of sessions over a more extended time. Regardless of the time frame, they all concluded that there were improvements in anxiety levels after PMR therapy sessions.

Most of the findings were expected, and they answered the PICO question being asked in the affirmative and gave credence to the proposed project. The only problem was the lack of articles on PMR for pre-IM injection or pre-ketamine infusion anxiety. However, there were enough articles surrounding PMR use in preprocedural or pre-stress-inducing events. The studies were mostly completed in a hospital setting, but the
findings should be generalizable to other settings with anxiety-producing activities. The findings are strong enough to support changing how practice is currently done.

**Rationale**

Jean Watson’s *Theory of Human Care* provided the framework for implementing this project. This theory encourages empathy and caring. It endorses a more open and emotional approach to caring for patients in healthcare. The foundation of this theory is that congruence, warmth, and empathy help develop a helping–trust relationship between the patient and the nurse (Watson, 2012). One way to promote a more positive experience in the healthcare environment is to encourage individuals to spiritually and authentically engage with patients and their families (Watson, 2012). For this project, Watson’s theory of human care was pivotal in forming and implementing brief PMR therapy to address a patient’s anxiety instead of brushing past it and moving on and promoting a more trusting relationship between the provider and the patient, which led to decreased patient anxiety.

The Plan-Do-Study-Act (PDSA) quality improvement model was also used to implement this project (Appendix K). Following these four steps, the project was broken down into steps that allowed the outcome to be evaluated, improved, and retested. This means that even though the project has been completed, should the clinic find it beneficial, they can continue improving the process with each cycle.

**Specific Aims**
This Quality Improvement (QI) project aimed to develop, implement, and evaluate a brief PMR intervention for patients within an outpatient clinic setting to manage anxiety. The project implemented brief PMR therapy at Kerstin Helgason NP to decrease anxiety in patients receiving IM injection ketamine-assisted therapy. The patients were educated on PMR and were asked if they were open to participating in the project. After permission was obtained, their anxiety levels were scored, they were guided through a brief PMR session, and their anxiety was again assessed to measure any improvement. By practicing PMR, the goal was for the patients to have decreased anxiety levels. Utilizing a five-point Likert scale, patients were scored before and after the brief PMR on their anxiety level to see if there was an immediate improvement from the intervention.

Methods

Context

The intervention took place at the Kerstin Helgason, NP office. The Kerstin Helgason, NP clinic is a private practice mental health clinic with one provider who sees patients with mental health disorders ranging from anxiety and mood disorders such as Major Depressive Disorder and Bipolar Disorder to personality disorders such as Borderline Personality Disorder and Schizoaffective Disorder to psychotic disorders such as Delusional Disorder and Schizophrenia. The key stakeholders in this project were the provider at the office and the patients. The provider was the one who held power over how and what kind of interventions could be wrought. They held the power to allow the project to go through or not be implemented. The patients were the ones who were ultimately affected by whether the PMR therapy intervention was used appropriately or
not used at all. They also held the power to decline to attempt the intervention, so it was up to those implementing to explain the reason behind the project and the potential benefits.

**Intervention**

The intervention was implementing a brief PMR therapy in patients who identified as having anxiety. It was done with patients at the office scheduled to receive an intramuscular injection of ketamine-assisted therapy. Whether they were experiencing anxiety due to a fear of needles and injections or if the anxiety was because they were nervous about trying a psychedelic to treat their mental health disorders, a brief PMR was utilized to address it. PMR is a relaxation technique anyone can implement to alleviate disruptive and disturbing emotional symptoms like anxiety (Star, 2020). It has been helpful in moments of nervousness or high stress (Star, 2020).

**Gap Analysis**

At the time of this project, no consistent therapy or relaxation techniques were used to address patient anxiety. The provider may talk through with the patient their emotions and the patient may have their own relaxation techniques. This project aimed to provide patients with a simple tool for their anxiety. A more in-depth look at the gap between the current state and the desired state around this project’s objective can be found in the Gap Analysis chart in Appendix A.

**GANTT**

To bridge the gaps, a timeline for the needed work to be done is outlined in Appendix E. Summer of 2022 saw the pre-requisite classes completed before the project could be
implemented. The project outline was completed between the fall of 2022 and the Summer of 2023 and implementation began. The post-intervention data was gathered from the Spring of 2023 through the Summer of 2023, the post intervention data was gathered and the write-up was done. In the Fall of 2023, the project was presented to USF.

*Work Breakdown Structure*

This project’s work breakdown structure (WBS) had four main parts (Appendix I). The first task that had to be done was research. Under this task, the literature search and article compilation were done. By completing the research, all the evidence-based research needed to ensure the project had the most relevant and optimal information for its implementation was done. The second task was to create a plan for the intervention. Under this section was choosing the intervention and completing the Prospectus. The Prospectus is a formal document that contains all the information on who, what, where, why, when, and how the project will be implemented. Once step two was complete, step three began. The intervention was developed, during which, the outline was created, and approval was obtained by the project’s advisor and Kerstin Helgason, NP clinic. After steps one through three were done, step four of the WBS was executed – project implementation.

*Responsibility/Communication Plan*

To ensure the project development stayed on the timeline, meetings were held with the site provider and with the project advisor (see Appendix H). Done in person and over video communication, staying in touch with the project advisor involved monthly
progress updates. In-person and video conferences with the site provider involved project updates, suggestions, and Q&A sessions to tailor the project the facility. Those were held every other month.

**SWOT**

Appendix C shows an outline of the SWOT for this project. The strengths of this project were in the organizational support it had. This project also had the potential to reduce pre-ketamine-assisted therapy injection anxiety. The biggest weakness lies in its small sample size and potential patient willingness to attempt PMR therapy. The project could have proved dead on arrival if they were not open to trying the therapy. The opportunities within this project were the potential to expand it into non-ketamine medication appointments. The threats involved in this project came from the patient’s willingness to participate in the therapy and if there were patient cancellations.

**Budget**

To determine the budget for the proposed intervention, several factors needed to be considered, training time with the provider lasted roughly 1 hour, costing $200. Each interaction with the patients specific to this project lasted about 30 minutes for the provider. As it was implemented with 16 patients, and the hourly rate for the provider is $200, the cost was $1,600. In total, the project cost $1,800 (see Appendix G).

**Return On Investment (ROI)**
ROI for this project comes from the potential that this intervention can lead to a 5-10% increase in new clients per month based on word of mouth on the benefits and patient-provider solid relationship that is fostered when utilizing this intervention. The provider sees between ten to twenty ketamine session patients a month, so a 5-10% would mean one to two new patients a month. At $400/session, that is a $400-$800 monthly increase in revenue (see Appendix M).

**Outcome Measures**

A five-point Likert scale was utilized to study this intervention’s outcome. Patients were asked to rate their anxiety on a scale from 1-5 before and after the PMR intervention. The anxiety scale asked between 1 and 5 as follows: 1 no anxiety, 2 mild anxiety, 3 moderate anxiety, four severe anxiety, and five very severe anxiety (see Appendix L). The point of using a one-question assessment to measure the patient’s anxiety was so that the patient was able to answer without thinking. This allowed them to at the very base level, state whether the PMR therapy intervention did decrease their overall anxiety. It prevented them from overthinking and had them give an almost yes or no answer. This assessment was reliable, giving a precise, in-the-moment level of their anxiety.

**Analysis**

Data analysis was performed using the Analyze Data tool through Excel. Baseline anxiety levels were compared with data obtained immediately following the brief PMR intervention using the paired t-test and the Wilcoxon signed-rank test. Paired t-tests assume the data sample is normally distributed, which is not always clear and is hard to
assume when there is a small sample size (Montgomery & Runger, 2003). Therefore, the data was also analyzed using the Wilcoxon signed-rank test. The Wilcoxon signed-rank test is nonparametric, meaning it does not assume the two samples are normally distributed (Montgomery & Runger, 2003). This makes it an excellent tool to use on paired data that does not have the assumption of paired normality (Montgomery & Runger, 2003). All values of $P<0.05$ were considered to be statistically significant.

**Ethical Considerations**

Jesuit values are a core part of the University of San Francisco learning experience. These values allow for a deeper connection and understanding of doing, seeing, and experiencing life in a way that allows the student to appreciate the touch of God more deeply in all around them. This project is strongly linked to the Jesuit value of “cura personalis” or “care of the person”. Cura personalis means caring for each aspect of the person to promote the well-being of the body, spirit, and mind (Vanadilok, 2022). In regard to the profession of nursing, this means addressing each part of the patients’ lives and how staff can positively impact them (American Nurses Association, 2015). This aligns with Provision 1 of the American Nurses Association Code of Ethics for Nurses, which states that nurses are to practice with respect and compassion for the inherent worth, dignity, and unique attributes of each person (American Nurses Association, 2015). The physical, emotional, and mental health of the patient, not just fixing their physical ailments and sending them on their way.

This project was approved by the University of San Francisco (USF) Doctorate in Nursing Practice (DNP) program as an Institutional Review Board (IRB) exempt quality
improvement project. No identifying data was stored or reported in the outcome measures or during data reporting and the anxiety scale ratings were kept anonymous to protect patient privacy.

**Results**

A total of sixteen patients, male and female ranging in age from 19 to 65, participated in the project. There was a statistically significant decrease in anxiety levels when analyzing the difference in pre-anxiety and post-anxiety levels after the brief PMR intervention using the paired t-test. The level of significance was 0.05 (this number is often used in analytic studies as the level of significance [Montgomery & Rugner, 2003]). The mean of the project was found to be 1.563 and the P-value was found to be 0.000. This analysis showed that the null hypothesis, which assumed no difference between the anxiety scores before and after the intervention, was rejected and that there was statistical significance with the intervention on anxiety. The completed paired t-test analysis table can be found in Appendix F.

The Wilcoxon signed-rank test was done and with the test statistic found to be 0 and a critical value of 29 (for Alpha of 0.05 and the sample size of 16 [Montgomery & Rugner, 2003]), the critical value was more significant than the test statistic. Therefore, they overwhelmingly reject the null hypothesis. There was a statistically significant decrease in anxiety levels found with this test on using the intervention. For a more in-depth look at the Wilcoxon signed-rank test see Appendix F.

**Discussion**
Summary

All aims for this project were found as expected. Utilizing brief PMR sessions before IM injection of ketamine-assisted therapy decreased the patient’s anxiety. Patients also stated that by participating in the PMR, they became more aware of their own bodies and were able to reflect on where they felt the anxiety being held in their bodies. The tone and verbiage used by the provider to administer the PMR contributed to the successful outcomes of this intervention. They were coming from a grounded space that allowed the patient to follow along and relax more in their center.

In addition to decreased anxiety levels, the brief PMR also built a more open and trusting relationship between the patient and the provider. Potential unexpected findings were that the brief PMR may also have been a significant factor in decreasing patient blood pressure measurements and that going into their psychedelic journey in such a relaxed state made for a different experience. Future research into these potential effects must be done to see if there is truly a correlation between the PMR and these additional outcomes.

Interpretation

These findings support the results of other studies that concluded PMR can reduce anxiety in patients receiving various procedures. Compared to the other studies discussed in the Available Knowledge section of this paper, this project was based on a brief version of PMR focusing on patients receiving IM ketamine-assisted therapy. The intervention time was short, so there was no measurement of this intervention’s long-
term changes. Strategic trade-offs for this intervention are that in the short term, it takes time for the provider to learn the PMR and to implement the PMR for patients. By addressing the anxiety early on however, in the long term, the intervention can prevent the patient from escalating into worsening panic or anxiety.

These findings imply that utilizing this intervention can positively impact the patient’s experience and enhance patient-provider relationships and trust. This project did not consider other potential causes for decreased anxiety levels and assumed the intervention was the leading cause of the changes in reported scores. The findings of this project supported the use of Watson’s *Theory of Human Care* by ensuring patients were provided with care and empathy around their anxiety. To spread this work into new areas, minimal training will need to be provided to providers and staff on how to perform PMR. Future implications include opportunities to research bigger sample sizes in different procedural areas and study the effect of PMR on blood pressure and psychedelic journey experiences.

**Limitations**

Limitations to the project are essential to note. While PMR therapy techniques are helpful, patients are only sometimes fully committed to investing in them. When the patients could not wholly immerse themselves in the relaxation session, the internal validity of the project could have been affected. To attempt to mitigate this, clear explanations of what PMR is, what the potential benefits are, and clear and concise instructions were provided to help the patients understand what they may gain from using PMR. The other limitation of this project was its small sample size.
Conclusions

This Quality Improvement project shows that brief PMR can be used to address anxiety levels immediately. This showed that there is a benefit to be found for patients in stressful situations by using a brief, non-invasive PMR intervention that can help patients manage their emotions as they come up in a non-pharmacological manner. Future research into the effects of brief PMR of blood pressure measurements and psychedelic journey experiences should be done to discover the correlation and if there is any significant benefit for those outcomes. The following steps should also include more studies into the effects of brief PMR for pre-procedural anxiety for larger sample sizes and in different procedural areas to get a complete picture of its effectiveness. There is potential for the spread of this intervention to benefit outpatient clinics and inpatient hospital units in various situations for multiple circumstances to assist patients with managing their anxiety and other areas of patient functioning.

Other Information

Funding

The author disclosed that no financial support supported this work in the design, implementation, interpretation, or reporting of this project.
References


## Appendix A

### Gap Analysis

**PROJECT NAME:** A Quality Improvement Project on Anxiety Management Before Ketamine-Assisted Psychotherapy

**PROJECT LEAD:** Kiera Paulo

**PROJECT OBJECTIVE:** Decrease anxiety in patients before IM injection of ketamine.

<table>
<thead>
<tr>
<th>CURRENT</th>
<th>DESIRED</th>
<th>GAP</th>
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</table>
| -Provider will sit and talk through the emotions with them | -Pts armed with tools to manage their anxiety  
- A consistent intervention to provide the patient with | -PMR therapy implementation at the site |
Appendix B

Statement Of Non-Research Determination

UNIVERSITY OF SAN FRANCISCO | School of Nursing and Health Professions

Doctor of Nursing Practice
Statement of Non-Research Determination (SOD) Form

The SOD should be completed in NURS 7005 and NURS 791E/P or NURS 749/A/E

General Information

<table>
<thead>
<tr>
<th>Last Name:</th>
<th>Paulo</th>
<th>First Name:</th>
<th>Kiera</th>
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<tr>
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<td>Semester/Year:</td>
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Chairperson Name: Dr. Radasa
Second Reader Name: Dr. Cleary
Advisor Name: Dr. Radasa

Project Description

1. Title of Project:

   A Quality Improvement Project on Anxiety Management Before Ketamine-Assisted Psychotherapy

2. Brief Description of Project *(Clearly state the purpose of the project and the problem statement in 250 words or less):*

   This project aims to provide brief progressive muscle relaxation therapy to patients experiencing anxiety pre-IM injection of ketamine-assisted therapy.

3. AIM Statement: What are you trying to accomplish?
To decrease patient anxiety using progressive muscle relaxation therapy at Kerstin Helgason, NP by pre- and post-anxiety assessments.

4. **Brief Description of Intervention** (150 words):

   A brief progressive muscle relaxation session with the patient before receiving the IM ketamine-assisted therapy injection.

4a. **How will this intervention be implemented?**

   This project will be implemented at Kerstin Helgason, NP. Before starting the project, a sit-down session with the provider will explain how the PMR will be implemented.

5. **Outcome measurements: How will you know that a change is an improvement?**

   Outcomes will be measured by comparing pre and post anxiety assessments.
   Patient confidentiality will be maintained as only the anxiety scores will be retained, and no HPI will be used.
DNP Statement of Determination
Evidence-Based Change of Practice Project Checklist*
*The SOD should be completed in NURS 7005 and NURS 791E/P or NURS 749/A/E

**Project Title:**
A Performance Improvement Project on Agitation Management in an Inpatient Non-Psychiatric Hospital Setting

<table>
<thead>
<tr>
<th>Mark an “X” under “Yes” or “No” for each of the following statements:</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tr>
<td>The aim of the project is to improve the process or delivery of care with established/accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The specific aim is to improve performance on a specific service or program and <strong>is a part of usual care</strong>. All participants will receive standard of care.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The project is <strong>not</strong> designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does <strong>not</strong> follow a protocol that overrides clinical decision-making.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does <strong>not</strong> develop paradigms or untested methods or new untested standards.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does <strong>not</strong> seek to test an intervention that is beyond current science and experience.</td>
<td>X</td>
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</tr>
<tr>
<td>The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.</td>
<td>X</td>
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<tr>
<td>The project has <strong>no</strong> funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.</td>
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<tr>
<td>The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., <strong>not</strong> a personal research project that is dependent upon the voluntary participation of colleagues, students and/or patients.</td>
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</tr>
<tr>
<td>If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: “This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board.”</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

**Answer Key:**
- If the answer to all of these items is “Yes”, the project can be considered an evidence-based activity that does **not** meet the definition of research. IRB review is not required. Keep a copy of this checklist in your files.
• If the answer to any of these questions is "No", you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used: http://answers.hhs.gov/ohrp/categories/1569

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**DNP Statement of Determination**

**Evidence-Based Change of Practice Project Checklist Outcome**

_The SOD should be completed in NURS 7005 and NURS 791E/P or NURS 749/A/E_

☑ This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). **Student may proceed with implementation.**

☐ This project involves research with human subjects and **must be submitted for IRB approval before project activity can commence.**

**Comments:**

---

**Student Last Name:** Paulo  
**Student First Name:** Kiera  
**Student Signature:** 

**Chairperson Name:** Dr. Radasa  
**Chairperson Signature:**

**Date:** 08/13/2023
## Appendix C

### SWOT Analysis

<table>
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<th><strong>STRENGTHS</strong></th>
<th><strong>WEAKNESSES</strong></th>
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<td>• Organizational support</td>
<td>• Small sample size</td>
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<tr>
<td>• Potential to reduce pre-ketamine-assisted therapy injection anxiety</td>
<td>• The patient’s willingness to attempt PMR therapy</td>
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<tr>
<th><strong>OPPORTUNITIES</strong></th>
<th><strong>THREATS</strong></th>
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<tr>
<td>• Expansion to non-ketamine medication appointments</td>
<td>• Patient appointment cancellations</td>
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<td></td>
<td>• The willingness to participate</td>
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Appendix D

Project Site Letter of Support

To: University of San Francisco DNP Program
Date: August 14, 2023
RE: DNP Project Letter of Support from Kerstin Helgason, NP Clinic

This is a letter of support for Kiera Paulo to implement her DNP Comprehensive Project: A Quality Improvement Project on Anxiety Management Before Ketamine Assisted Psychotherapy at Kerstin Helgason, NP Clinic.

We give her permission to use the name of our agency in her DNP Comprehensive Project Paper and in future presentations and publications.

Sincerely,

Kerstin Helgason
Psychiatric Mental Health Nurse Practitioner
Mental Health Medicine, Ketamine Therapy, and Psychotherapy
# Appendix E

## GANNT Chart

<table>
<thead>
<tr>
<th>Project title</th>
<th>A Quality Improvement Project on Anxiety Management Before Ketamine Assisted Psychotherapy</th>
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<td>Company name</td>
<td>University of San Francisco/Salinas Valley Memorial Hospital</td>
</tr>
<tr>
<td>Project lead</td>
<td>Kiera Paulo</td>
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<tr>
<th>Milestone description</th>
<th>Progress</th>
<th>Start</th>
<th>Months</th>
<th>2022</th>
<th>2023</th>
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<td>5/23/2022</td>
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<td>DNP Post Project Write Up</td>
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<td>DNP Post Project Write Up</td>
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<td><strong>Fall Term</strong></td>
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<tr>
<td>N789: DNP Project Presentation</td>
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## Appendix F

### Final Report Display Tables

#### t-Test: Paired Two Sample for Means

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>After</th>
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<tbody>
<tr>
<td>Mean</td>
<td>2.5</td>
<td>1.5625</td>
</tr>
<tr>
<td>Variance</td>
<td>0.533333</td>
<td>0.395833</td>
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<td>Observations</td>
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<td>16</td>
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<tr>
<td>Hypothesized Mean</td>
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<td></td>
</tr>
<tr>
<td>df</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>t Stat</td>
<td>8.47399</td>
<td></td>
</tr>
<tr>
<td>P(T&lt;=t) two-tail</td>
<td>4.21E-07</td>
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</table>

#### Wilcoxon Signed-Rank Test

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<th>Before</th>
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<th>Sign</th>
<th>Absolute Value</th>
<th>Signed-Rank</th>
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<tr>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>2</td>
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<tr>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>

Positive Sum: 133
Negative Sum: 0
Critical Value: 29 (for alpha of .05 and sample size of 16)

Reject Null Hypothesis when test statistic is less than critical value
Therefore, reject null hypothesis that there is no difference between anxiety level before the treatment and after the treatment
### Appendix G

**Budget**

<table>
<thead>
<tr>
<th>Service</th>
<th>Unit/0.5 Hour</th>
<th>Rate</th>
<th>Cost</th>
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<tbody>
<tr>
<td>In Person Interaction NP 30 Min</td>
<td>16</td>
<td>100</td>
<td>$1,600.0</td>
</tr>
<tr>
<td>Clinical Educator Time</td>
<td>1</td>
<td>200</td>
<td>$200.0</td>
</tr>
<tr>
<td><strong>Total Cost</strong></td>
<td></td>
<td></td>
<td><strong>$1,800.0</strong></td>
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## Appendix H

### Responsibility/Communication Matrix

<table>
<thead>
<tr>
<th>COMMUNICATION</th>
<th>PURPOSE</th>
<th>MEDIUM</th>
<th>FREQUENCY</th>
<th>AUDIENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advisor Meeting</td>
<td>Project progress update.</td>
<td>In person or video</td>
<td>As needed.</td>
<td>Advisor</td>
</tr>
<tr>
<td>Site Meetings</td>
<td>Update on current project status.</td>
<td>In person</td>
<td>As needed</td>
<td>Kerstin Helgason</td>
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</tbody>
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Appendix I

Work Breakdown Structure

Implement Project

Research
- Lit Search
- Article Compilation

Create Plan
- Select Intervention
- Write Prospectus

Develop Intervention
- Create Outline
- Get Advisor Approval
### Appendix J
#### Evaluation Tables

<table>
<thead>
<tr>
<th>Purpose of Article or Review</th>
<th>Design / Method / Conceptual Framework</th>
<th>Sample / Setting</th>
<th>Major Variables Studied (and their Definitions)</th>
<th>Measurement of Major Variables</th>
<th>Data Analysis</th>
<th>Study Findings</th>
<th>Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-To see if PMR could reduce anxiety in nursing students who were doing clinical simulations.</td>
<td>-Pilot study -Experimental group that listed to prerecorded PMR audio and control group that did not -Cognitive interface theory</td>
<td>-15 associate degree nursing students -University of Alaska Anchorage</td>
<td>-Pre and post anxiety levels</td>
<td>-State Trait Anxiety Inventory (STAI)</td>
<td>-Shapiro-Wilk test, independent t-tests</td>
<td>-There was a statistically significant decrease in the STAI scores of the experimental group compared to the control group</td>
<td>-Level IV -Produced results that support the use of PMR to decrease anxiety -Weakness include the small sample size -Results support the potential benefits of PMR in decreasing anxiety -Since anxiety can interfere with student learning during simulation, it may be beneficial to teach students an easy technique to lower their anxiety levels -More studies should be conducted to determine if there is more support for the use of PMR</td>
</tr>
</tbody>
</table>

### APA Reference:

<table>
<thead>
<tr>
<th>Purpose of Article or Review</th>
<th>Design / Method / Conceptual Framework</th>
<th>Sample / Setting</th>
<th>Major Variables Studied (and their Definitions)</th>
<th>Measurement of Major Variables</th>
<th>Data Analysis</th>
<th>Study Findings</th>
<th>Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Determine the effects of PMR on anxiety levels of mothers before sectio caesarea</td>
<td>-Quasi-experimental non-equivalent control group design -Pretest-postest control group design where the experimental and control groups are not chosen randomly</td>
<td>-36 respondents -Dinda Hospital</td>
<td>-Anxiety levels</td>
<td>-Zung Self-Report Anxiety Scale (ZSAS)</td>
<td>-Independent paired t-test</td>
<td>-PMR can reduce anxiety levels</td>
<td>-Level III -Produced results that support the use of PMR to decrease anxiety levels -Weaknesses of the article lie in the small sample size -Results support the potential benefits of PMR in decreasing anxiety -Results of the analysis show that the provision of PMR techniques can reduce anxiety levels -Hospitals need to implement non-pharmacological policies to reduce mother anxiety levels through PMR techniques before sectio caesarea surgery</td>
</tr>
</tbody>
</table>

Definition of abbreviations: PMR – progressive muscle relaxation

<table>
<thead>
<tr>
<th>Purpose of Article or Review</th>
<th>Design / Method / Conceptual Framework</th>
<th>Sample / Setting</th>
<th>Major Variables Studied (and their Definitions)</th>
<th>Measurement of Major Variables</th>
<th>Data Analysis</th>
<th>Study Findings</th>
<th>Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s)</th>
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<tr>
<td>To test the effectiveness of guided imagery (GI) and PMR as stress reducing interventions in patients with prostate and breast cancer undergoing chemotherapy</td>
<td>Randomized Controlled Trial</td>
<td>208 patients</td>
<td>Anxiety levels</td>
<td>-Zung Self-Rating Anxiety Scale, Beck Depression Interview II</td>
<td>-t-test for independent samples</td>
<td>-Pts with prostate or breast cancer undergoing chemotherapy can benefit from PMR and GI sessions to reduce depression and anxiety</td>
<td>Level II -Produced results that support the use of PMR and GI to decrease anxiety and depression levels -Participants were not blinded, only assessors were -Results support the potential benefits of PMR in decreasing anxiety -Pts with prostate or breast cancer undergoing chemotherapy can benefit from PMR and GI sessions to reduce depression and anxiety -Study the long-lasting effects of PMR and GI</td>
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Definition of abbreviations:
### Purpose of Article or Review

- Assess the impact of an expressive arts therapy combined with PMR in pts with gynecological malignancies undergoing surgery

### Design / Method / Conceptual Framework

- Prospective, non-randomized controlled trial
- Intervention and control group

### Sample / Setting

- 116 pts
- Jinjiang District of West China Second University Hospital

### Major Variables Studied (and their Definitions)

- Anxiety, depression, and hope

### Measurement of Major Variables

- Hospital anxiety and depression scale (HADS), Herth hope index (HHI), state anxiety inventory (SAI)

### Data Analysis

- Paired sample t-test

### Study Findings

- Expressive arts therapy combined with PMR is ineffective in reducing immediate anxiety

### Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s)

- Level III
- Produced results that support the use of PMR and GI to decrease anxiety and depression levels
- Small sample size
- Results support the potential benefits of PMR in decreasing anxiety
- The study showed that expressive arts therapy combined with progressive muscle relaxation following music administered by nurses was effective in reducing patients’ immediate anxiety
- Further expressive arts therapy studies examine the impact of patient-tailored arts therapy interventions on spiritual well-being in patients with gynecological malignancies, especially in the perioperative period

### APA Reference

<table>
<thead>
<tr>
<th>Purpose of Article or Review</th>
<th>Design / Method / Conceptual Framework</th>
<th>Sample / Setting</th>
<th>Major Variables Studied (and their Definitions)</th>
<th>Measurement of Major Variables</th>
<th>Data Analysis</th>
<th>Study Findings</th>
<th>Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s)</th>
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<tbody>
<tr>
<td>Determine whether PMR therapy could relieve dental anxiety</td>
<td>-Randomized Controlled Trial -Intervention and control groups. The intervention group provided PMR therapy 15 minutes before periodontal treatment</td>
<td>-68 periodontal patients -Dental clinic in Incheon, Republic of Korea</td>
<td>-Anxiety, depression</td>
<td>-DAS, Beck depression inventory</td>
<td>-Wilcoxon rank-sum test, chi-square test, or Fisher exact test</td>
<td>-Demonstrated an association between progressive muscle relaxation therapy and the relief of dental anxiety</td>
<td>-Level II -Produced results that support the use of PMR and GI to decrease anxiety and depression levels -Small sample size -Results support the potential benefits of PMR in decreasing anxiety -Demonstrated an association between progressive muscle relaxation therapy and the relief of dental anxiety -Studies involving more extended follow-up periods are required to determine the duration of the effects of progressive muscle relaxation therapy</td>
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</tbody>
</table>

<table>
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<tr>
<th>Purpose of Article or Review</th>
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<th>Measurement of Major Variables</th>
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<th>Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s)</th>
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</thead>
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<tr>
<td>Evaluate the impact of PMR on state anxiety and self-efficacy in hospitalized pts admitted for extremity fracture receiving elective surgery</td>
<td>Randomized controlled clinical study</td>
<td>90 patients within 48 hours of their admittance to the hospital</td>
<td>Anxiety</td>
<td>State anxiety inventory and self-efficacy scales</td>
<td>Paired-sample t-tests, independent t-tests</td>
<td>PMR is effective in reducing state anxiety and enhancing the self-efficacy of patients with extremity fracture undergoing an elective surgery</td>
<td>Level II</td>
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Appendix K

IHI PDSA Plan

ACT

- Assess improvement of anxiety from progressive muscle relaxation therapy.

PLAN

- Design the training information within the site.
- Decide/create the anxiety assessment tool.

STUDY

- Analyze pre to post patient anxiety levels.

DO

- Implement training at site.
- Collect pre and post intervention data.
Appendix L

Anxiety Assessment

<table>
<thead>
<tr>
<th>ANXIETY LEVEL</th>
<th>Description</th>
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<tr>
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</tr>
<tr>
<td>2</td>
<td>Mild</td>
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<tr>
<td>3</td>
<td>Moderate</td>
</tr>
<tr>
<td>4</td>
<td>Severe</td>
</tr>
<tr>
<td>5</td>
<td>Very Severe</td>
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## Appendix M

### Return On Investment

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<th>Month 3</th>
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<tr>
<td>Ketamine-Assisted Therapy Revenue</td>
<td>$4,000-$8,000</td>
<td>$4,400-$8,800</td>
<td>$4,800-$9,600</td>
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<tr>
<td>Total Revenue Increase from Month 1</td>
<td>$400-$800</td>
<td>$800-$1,600</td>
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*Provider sees 10-20 ketamine pts per month ($400/session), assuming a 5-10% increase in new patients due to PMR*