

Philadelphia College of Osteopathic Medicine

DigitalCommons@PCOM

PCOM Physician Assistant Studies Student
Scholarship

Student Dissertations, Theses and Papers

2022

Does medical clowning impact anxiety in the pediatric population undergoing medical interventions?

Kelso Blaze

Philadelphia College of Osteopathic Medicine

Follow this and additional works at: https://digitalcommons.pcom.edu/pa_systematic_reviews



Part of the [Medicine and Health Sciences Commons](#)

Recommended Citation

Blaze, Kelso, "Does medical clowning impact anxiety in the pediatric population undergoing medical interventions?" (2022). *PCOM Physician Assistant Studies Student Scholarship*. 653.

https://digitalcommons.pcom.edu/pa_systematic_reviews/653

This Selective Evidence-Based Medicine Review is brought to you for free and open access by the Student Dissertations, Theses and Papers at DigitalCommons@PCOM. It has been accepted for inclusion in PCOM Physician Assistant Studies Student Scholarship by an authorized administrator of DigitalCommons@PCOM. For more information, please contact jaclynwe@pcom.edu.

Does medical clowning impact anxiety in the pediatric population undergoing medical interventions?

Kelso L. Blaze, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies Philadelphia College of Osteopathic Medicine

Philadelphia, Pennsylvania

July 31, 2022

Acknowledgement

"I dove into an endless sea of gratitude from which I've never emerged." -Patch Adams, M.D.

Thank you Dr. Guinane, PCOM, and all the friends who helped this clown along the way.

INTRODUCTION

Medical interventions can be stressful enough in terms of outcomes and finances.

Performing these procedures on our precious pediatric population amplifies this pressure. The diverse range of development within this constantly evolving demographic entertains a wide realm of coping mechanisms and a gamut of emotional and physical development. There are an estimated 3.9 million pediatric surgeries every year.¹ This number fails to include more general medical interventions such as emergency room visits, routine physicals, blood draws, etc.¹ Total cost of caring for pediatric patient anxiety, including time spent to soothe the child, has yet to be reliably quantified. However, the prospect to polish the pediatric patient experience is priceless.

Anxiety's ancient origin encapsulates a labyrinth of neuro-biological communications for survival. Like the strings of a puppet, anxiety manipulates our action's based on perceived stress. Its pathophysiology is a complex and multi-faceted carnival of its own, consisting of the central nervous system utilizing gamma-aminobutyric acid (GABA), norepinephrine, serotonin, and dopamine. These entities are then mediated by our autonomic nervous system, especially the sympathetic branch, along with our emotions, surroundings, and additional stimuli. Do not be a *nincompoop* and mistake this with formal psychological medical diagnoses, such as generalized anxiety disorder. Rather, the object of this paper is improving outcomes like pain and cost reduction by focusing on anxiety experienced by the pediatric patients.

Current techniques for pre-procedural pediatric perturbations are comical. These include relying on the caretaker for assistance, along with pharmacologic sedatives (midazolam,

clonidine), and anesthetic agents (ketamine, fentanyl) which are associated with adverse side effects such as dramatic changes in blood pressure or vision, gastrointestinal issues, and in some cases, fatality. Alternative options are needed to aid the delivery of superb medical care for pediatric patients.

Medical clowning is a therapeutic technique utilizing modalities such as humor, improv, circus, puppetry, and more to aid the healing process, and foster trust between patients and their healthcare team.² This modality may serve as a cost-effective alternative to caretaker and pharmacologic options and potentially improve patient-oriented outcomes through a personalized approach.³ Play is essential to a child's growth, rendering benefits socially, emotionally, cognitively, and physically.⁴ Unfortunately, those who grow up living with chronic medical conditions are more likely to miss this vital aspect of development. Art therapies have been shown to benefit identification and expression of one's emotions, manifesting more effective coping mechanisms and subsequent improved communication with loved ones and the healthcare team.⁵ Humor therapies have shown auspicious effects on stress and cortisol levels of pediatric in-patients.⁶ Laughter can increase blood circulation, and improves cardiovascular and immune function.⁶ This paper evaluates three randomized controlled trials (RCTs), assessing medical clown's impact on anxiety in pediatric patients undergoing medical interventions.

OBJECTIVE

The objective of this selective EBM review is to determine, "Does medical clowning impact anxiety in pediatric patients undergoing medical interventions?"

METHODS

Research articles were chosen based on criteria including relevance to the clinical inquiry and use of patient-oriented outcomes (POEMS). The studies selected investigated similar

populations with a similar intervention, comparison group, and measured outcomes. It was required all research articles investigated pediatric patients undergoing medical interventions and measured their corresponding anxiety either with or without a medical clown. This review references three research articles found on PubMed using keywords “clown” and “anxiety”. Criteria includes a peer-review article publication and use of randomization within their research. All three were published in English. Inclusion criteria consisted of RCTs published between 2012-2021, excluding any studies published outside this time frame. Populations included humans between 2-12 years of age. These studies utilized statistical analysis to determine the mean change from baseline, using a scale comprised of visual analogs featuring a range of facial expressions from calm to distressed. Assessment of clinical significance was calculated utilizing p-values. In this selective EBM review, these studies investigated the pediatric population. These studies demographics and defining features can be found in Table 1. Interaction with a medical clown served as the intervention in all three studies. All three authors utilized a no clown interaction control group for comparison. Anxiety level in pediatric patients undergoing medical interventions is the outcome measured and discussed in this selective EBM review. This paper evaluates three randomized controlled trials (RCTs), assessing the efficacy of medical clowning as a potential management option for anxiety experienced in pediatric patients undergoing while medical interventions.

OUTCOME MEASURED

Anxiety’s nature encapsulates a subjective component, independent of heart rate or physiologic signs of stress. Thus, it is inherently difficult to objectively quantify. To better assess the individual’s experience, various scales have been developed. Meiri et al. and Felluga et al. both utilized a type of Visual Analog Scale (VAS) ranging from 1-5 or 1-10, respectively.^{7,8}

Each number corresponded to facial expression which escalated emoted distress as the numerical value increased. For example, a smiling and calm or the “least anxious” expression corresponds to a “1” numerically, with the most distressed or anxious face correlating to the highest number, like “10.” Thus, a higher numerical value correlates to a greater level of anxiety experienced.

Data was recorded by a various sources depending on the study.

Meiri et al. employed the pediatric patient and their caretaker(s) to record anxiety. The caretaker marked the point where the child pointed to express their emotion.⁷ This line was measured in centimeters from the scales starting value.⁷ Meiri et al. followed up via telephone with the caretaker 24 hours after the encounter to record future anxiety relating to medical procedures.⁷ Felluga et al. utilized a trained psychologist to measure anxiety initially in the waiting area, and again upon the procedure’s cessation with a VAS-like measure, the Children’s Anxiety and Pain Scale (CAPS).⁸ Dionigi et al. utilized a “Modified Yale Preoperative Anxiety Scale” (m-YAS) which consists of 22 items cataloged into 5 behavior domains (activity, emotional expressivity, state of arousal, vocalization, and use of parents) to assess anxiety.⁹ A trained psychologist used this scale to rate the children’s anxiety in both the waiting room and pre-operative area.⁹ Although not identical, these measuring techniques are of a similar enough nature to be used for comparison across these three studies.

Table 1. Demographics & Characteristics of Included Studies

Study	Type	# of Pts.	Age (yrs.)	Inclusion Criteria	Exclusion Criteria	W / D	Interventions
Dionigi (2014) ⁹	RCT	52	2-12	Patients 2-12 years old who underwent general anesthesia for otolaryngologic surgery; parents consented to study; parents able to understand the questionnaire.	Children younger than 2 years or older than 12 years; parents that did not agree to take part in the study, and parents who were not able to understand and answer the questionnaire.	0	Interacting with a clown (using puppets, bubbles, etc. with one child at a time for) 30 minutes, prior to their medical procedures vs. a control group of no clown.
Felluga (2016) ⁸	RCT	40	4-11	Children (4-11 years old) admitted to the Emergency Department in need of painful procedures; Not pre-medicated with drugs; parental consent given.	Children younger than 4 years old or older than 11 years old; pre-medicated with drugs prior to procedure; parental consent denied.	0	Interaction with two clowns (juggling, improv, etc. for 20 minutes before the procedure and in the ED throughout the procedure. vs. control group (no clown interaction)
Meiri (2016) ⁷	RCT	100	2-10	2–10 years old, who needed line insertion or blood sampling for clinical reasons; children must not be acutely ill or unstable in a medical sense; parental consent.	Children less than 2 years old or older than 10 years old; Parental consent not given, if child was acutely ill or unstable.	0	Medical intervention with clown present (starting 10 minutes before procedure until child left the procedural room). vs. control group- medical intervention without clown interaction.

RESULTS

All three studies in this selective review enrolled pediatric patients about to undergo medical interventions to determine whether medical clowns impacted their anxiety. Dionigi et al. conducted a randomized controlled trial that enrolled children between 2-12 years of age who were about to undergo a medical intervention, specifically general anesthesia for otolaryngologic surgery.⁹ The study was conducted over the course of a single medical visit and compared to the control group with no medical clown intervention.⁹ The change in anxiety pre-procedure to post-procedure is the primary outcome investigated in this research.⁹ The cohort consisted of 77 children who were randomly assigned in a ratio of 2:1 to either the medical clown intervention (CoG) or control group (CG).⁹ In total, 52 patients received clown intervention, while 22 patients in the control group did not.⁹ This study's nature makes blinding of participants near impossible. To participate, caretakers, healthcare professionals, and clowns consented, thus, were made known of the treatment assignment.⁹ A trained psychologist rated the children's anxiety using the m-YAS in both the waiting room, along with the pre-operation room.⁸ No adverse events or loss of subjects were reported during this trial.⁹

Assessments for impact of anxiety based on the Modified Yale Preoperative Anxiety Scale (m-YPAS) were observed after the medical intervention.⁹ Mean values were calculated by the authors and used to measure outcomes between clown interaction and the control group. The results were statically significant ($P < 0.004$) in both interventions. The clown group showed a decrease in mean values with 50 pre-procedure and 33 after clown interaction, resulting in a mean change from baseline of 17.⁹ The control group demonstrated an increase from 33 before procedure to 43 after the procedure, resulting in a mean change of baseline of 10.⁹ These results are summarized in Table 2 below. Compared to the control group, medical clowning was found

to be a superior intervention, shown by the 17-point difference between groups.⁹ These findings convert to a large treatment impact, with decrease from pre-procedure baseline to post procedure.

Table 2. Modified Yale Preoperative Anxiety Scale (m-YPAS) Change in Anxiety from Baseline to Interaction with Medical Clown.⁹

	Before Procedure (Mean)	After Procedure (Mean)	Mean Change from Baseline	P-Value
Clown Group (CG)	50	33	17	P < 0.004
Control (CoG)	33	43	+ 10	P < 0.004

Felluga et. al conducted a trial of a similar design as Diogini et al., however their studies had subtle differences. Whereas Diogini et. al. focused more so on 2–12-year-old patients hospitalized for minor surgery, Felluga et. al. studied 4–11-year-old patients admitted to the emergency department (ED) for a painful procedure.^{8,9} Felluga et al. conducted a randomized controlled trial, enrolling these 4–11-year-old patients who came to the ED for a painful procedure.⁸ Unfortunately, blinding of raters was implausible due to the nature of this study. The study was conducted over the course of a day and compared clown interaction prior to the procedure to the control group (no clown intervention).⁸ Anxiety levels determined by the CAPS scale is the primary outcome examined at the end of the day.⁸ The cohort consisted of 40 patients who were randomized based on their ED arrival time.⁸ In total 40 patients were enrolled in the study and then were split into the two groups, the control, and the clown interaction group, comprised of 20 participants each.⁸ No adverse effects or incidences were reported with use of clown interaction.⁸ All subjects enrolled finished the study and were included in the primary data analysis and a worst-case analysis was not performed.⁸ Assessments for efficacy and improvement in anxiety were observed after that single encounter and demonstrated a decrease in mean values with 2 ± 0.759 prior to treatment.⁸ Post treatment the clown group demonstrated a

mean and standard deviation of 1 ± 0.013 with the control group demonstrating a 2 ± 0.013 with a confidence interval of $P < 0.05$ (Table 3).⁸

Table 3. Children’s Anxiety and Pain Scale (CAPS) Change in Anxiety from Baseline to Interaction with Clown.⁸

	Before Procedure (Mean±SD)	After Procedure (Mean±SD)	Mean Change from Baseline	P-Value
Clown Group (CG)	2 ± 0.759	1 ± 0.013	1	$P < 0.05$
Control (CoG)	2 ± 0.759	2 ± 0.013	0	$P = 0.05$

Meiri et. al conducted a trial of a similar design as Diogini et al. and Felluga et. al., however, their patient population consisted of 2–10 years old who needed line insertion or blood sampling for clinical reasons.^{7,8,9} Meiri et al. conducted a randomized controlled trial, enrolling these 2–10-year-old patients who needed line insertion or blood sampling for clinical reasons.⁷ Complete blinding of raters did not occur due to the study’s inherent design. The study was conducted over the course of the procedure’s length and compared clown interaction prior to the procedure to the control group (no clown intervention).⁷ Anxiety levels determined by the VAS scale served as the primary outcome investigated after their procedure.⁷ The cohort consisted of 100 patients undergoing blood exams.⁷ This study measured two variables (clown interaction vs. topical analgesic) and a control group (no clown interaction).⁷ The 100 children were first split into the two groups, with 41 patients undergoing the blood exam with IV cannulation, and 59 undergoing the blood exam without IV cannulation.⁷ The medical clown group was randomized in a 3:1 nature.⁷ The control (no clown interaction) group consisted of 33 children.⁷ The authors did not note a specific value for participants in the clown group, but stated it consisted of 20 boys and mentioned an estimated 1.12 male to female ratio.⁷ Authors measured a third variable, which was out of scope for our analysis. No adverse incidents due to interaction with clown were

noted.⁷ All subjects enrolled finished the study and were included in the primary data analysis. A worst-case analysis was not pursued. Assessments for efficacy and improvement in anxiety were observed after that single encounter and demonstrated a decrease in mean values with 3.0 ± 3.2 in the clown interaction group and 6.3 ± 3.3 in the control group prior to treatment.⁷ Post treatment the clown group demonstrated a mean and standard deviation of 2.6 ± 1.2 with the control group value of 3.8 ± 1.6 with a confidence interval of $P < 0.05$ (Table 4).⁷

Table 4. A scale like the Visual Analogue Scale (VAS) measuring Change in Anxiety from Baseline to Interaction with Clown⁷

	Before Procedure (Mean \pm SD)	After Procedure (Mean \pm SD)	Mean Change from Baseline	P-Value
Clown Group (CG)	3.0 ± 3.2	2.6 ± 1.2	0.4	$P < 0.05$
Control (CoG)	6.3 ± 3.3	3.8 ± 1.6	2.5	$P = 0.05$

DISCUSSION

It is estimated that ~3.9 million pediatric surgeries every year in the United States, and even more emergency department visits, routine blood draws, etc.¹ The immense stress from a pediatric medical issue mirror that of walking a tight rope or being shot out of a cannon. Thus, strategies to manage pre-procedural pediatric anxiety may elicit more positive outcomes, with the overall goal of polishing pediatric patient experience. Current modalities, like pharmacologic agents, relying on caretaker assistance, or in some cases, no treatment, are used. These options may have a detrimental impact, such as unwanted side effects from pharmacologic treatments, un-fairly putting caretakes in uncomfortably liable positions, or aversion of future healthcare due to deep seeded medical anxiety. Thus, there is a necessity for creative cost-effective alternatives. Medical clowning has several barriers. The medical clown would need to harness the skills of a

serious medical professional practicing the art AND science of medicine safely, while costumed as a light-hearted buffoon ensuring the whole troupe, including family and staff, have efficacious outcomes. Another barrier may be insurance companies thinking clinical clowns are a joke, thus not covering costs due to the current lack of research on medical clowning's financial benefit.

This review evaluated the efficacy of medical clowning as a treatment for anxiety sensed among pediatric patients undergoing medical interventions. All three studies stated statistically significant reduction anxiety, using their respective p-values, after intervention with a medical clown. Only two of the three studies, Diogini and Meiri, demonstrated substantial mean change in baseline and large treatment effect sizes, while Felluga demonstrated a small treatment effect size and their mean change in baseline was not substantial.^{7,8,9} These conflicting results, in conjunction with further scrutiny of their research methods, makes for answering the clinical question of, "whether medical clowning impacts pediatric patients' anxiety," inconclusive.

All three studies had limitations. The participants in the study, including raters recording anxiety, were unable to be "blinded" from the treatment groups due to the inherent nature of this research. This may lead to inaccurate results because subjects are aware of who is interacting with the clown. This bias would most likely lean towards clowning, considering most all subjects consented to the potential of clown intervention. Thus, it would falsely demonstrate a reduction in anxiety upon clown intervention. Other limitations include lack of generalizability, due to the unique locations like Felluga et al. in emergency department in Italy, or Dionigi et al. in an Israeli clinic, and their wide age range, 2-10 years old.^{8,9} Felluga et al. and Dionigi et al. were limited with their sample sizes being less than or about 50 participants, thus limiting the reliability and validity of their findings.^{8,9} No study lost participants and worst-case analysis were not

performed. Dionigi et al. follow up was within 30 minutes, thus not as sufficient in determining the true treatment's impact.⁹ Another concerning factor in Dionigi et al. study with the difference between their control and treatment group's pre-procedural anxiety, suggesting our pre-intervention groups were not similar from the start.⁸ These factors negatively impact validity.

CONCLUSION

Although showing positive potential, this systematic review was inconclusive in determining whether medical clowning benefitted reduction in anxiety among pediatric patients. Although the researcher's statistics and words align with statistical significance, closer scrutiny of these methods elicited areas of improvement before successful application in clinical practice. Despite the issues, Mieri et al., Felluga et al., and Dionigi et al. all found medical clowning to have a statistically significant mean decrease in pediatric procedural anxiety upon medical intervention.^{7,8,9} Thus, the chance of improving the pediatric patient experience for all involved, with goals of shrinking the cost, pharmaceutical use, and psychological impact on such an impressionable population, is worthy of further scientific investigation. Such investigations should focus on making the studies more generalizable. For example, using a single medical setting like the Emergency Department or a more focused age range, say 5-6 years old instead of the more developmentally dramatic 2-10 years old. More focused research could parse out which medical settings, procedures, and developmental stages medical clowning would be optimal in. It is vital their treatment groups are similar from the start and follow up is sufficient. Future researcher should investigate techniques for a medical clown's training and successful incorporation into the medical team's existing circus of operation. This may ensure full clinical benefit during these vital procedures. These three studies analyze acute medical scenarios, whereas medical clowning may serve a fruitful place in the management of chronic conditions.

This would aid other medical incentives such as continuity of care and reduction in cost and pain. It would also allow for clowning, playfulness, and humor within a hyper-vigilant setting. After all the mind, body, and spirit kinship exemplify the deeply interwoven nature between mental and physical health. Comedy is famously defined as tragedy plus time. Taking time to further research potential benefits upon “sending in the clowns,” may lessen pediatric emotional and physical tragedies.

Although some aspects of these studies may be “laughable,” further investigation of medical clowning should be taken seriously. A red nose may help an erythematous nose after all. The potential medical clowning encompasses may benefit all parties involved in pediatric patient care, including those of the birthday variety. In the words of Dr. Patch Adams, M.D. a social activist clown, “humor is an antidote to all ills.” He prescribed, “the purpose of a doctor or any human in general should not be to simply delay the death of the patient, but rather to increase the person’s quality of life.” Don’t let the unicycle, red shoes, or rubber chicken fool you. A clown’s role within a medical team’s own circus of operation should not be taken as a joke.

References

1. Rabbitts, JA, Groenewald, CB. Epidemiology of pediatric surgery in the United States. *Pediatr Anesth*. 2020; 30: 1083– 1090. <https://doi.org/10.1111/pan.13993>
2. Finlay F, Baverstock A, Lenton S. Therapeutic clowning in paediatric practice. *Clin. Child Psych. and Psy*. 2014;19(4):596-605. doi:10.1177/1359104513492746
3. Javed T, Khan AS, Jarral NA, Taqi Z, Raza M, Shahid Z. Medical clowning: a cost-effective way to reduce stress among children undergoing invasive procedures. *Cureus*. 2021;13(10):e18886. Published 2021 Oct 19. doi:10.7759/cureus.18886
4. Nijhof SL, Vinkers CH, van Geelen SM, et al. Healthy play, better coping: The importance of play for the development of children in health and disease. *Neurosci Biobehav Rev*. 2018;95:421-429. doi:10.1016/j.neubiorev.2018.09.024
5. Aguilar BA. The Efficacy of Art Therapy in Pediatric Oncology Patients: An Integrative Literature Review. *J Pediatr Nurs*. 2017;36:173-178. doi:10.1016/j.pedn.2017.06.015
6. Sánchez JC, Echeverri LF, Londoño MJ, et al. Effects of a humor therapy program on stress levels in pediatric inpatients. *Hosp Pediatr*. 2017;7(1):46-53.
7. Meiri N, Ankri A, Hamad-Saied M, Konopnicki M, Pillar G. The effect of medical clowning on reducing pain, crying, and anxiety in children aged 2-10 years old undergoing venous blood drawing--a randomized controlled study. *Eur J Pediatr*. 2016;175(3):373-379. doi:10.1007/s00431-015-2652-z
8. Felluga M, Rabach I, Minute M, Montico M, Giorgi R, Lonciari I, Taddio A, Barbi E. A quasi randomized-controlled trial to evaluate the effectiveness of clowntherapy on children's anxiety and pain levels in emergency department. *Eur J Pediatr*. 2016 May;175(5):645-50. doi: 10.1007/s00431-015-2688-0.
9. Dionigi A, Sangiorgi D, Flangini R. Clown intervention to reduce preoperative anxiety in children and parents: a randomized controlled trial. *J Health Psychol*. 2014 Mar;19(3):369-80. doi: 10.1177/1359105312471567.
10. Basel A, Bajic D. Preoperative evaluation of the pediatric patient. *Anesthesiol Clin*. 2018;36(4):689-700. doi:10.1016/j.anclin.2018.07.016

Abstract

1. **OBJECTIVE:** The objective of this selective EBM review is to investigate the question, “does medical clowning impact anxiety in the pediatric patient undergoing medical interventions?”
2. **STUDY DESIGN:** Review of three randomized control trials (RCT).
3. **DATA SOURCES:** These articles were published between 2012-2021 in English. The in peer-reviewed journals, searched for using PubMed.
4. **OUTCOME(S) MEASURED:** The outcomes measured included anxiety level in pediatric patients undergoing medical interventions.
5. **RESULTS:** In the RCT led by Dionigi et al., medical clowning led to a reduction in pediatric patient anxiety compared with the control group ($P < 0.005$), indicated by a mean change from baseline of 17. In the RCT by Felluga et al., medical clowning led to a reduction in pediatric patient anxiety compared with the control group ($P < 0.05$), indicated by a mean change from baseline of 1. Lastly, Mieri et al. demonstrated a reduction pediatric patient anxiety with medical clowning, indicated by a mean change from baseline of 0.04 with statistical significance of $P < 0.05$ in the treatment group.
6. **CONCLUSION:** All three studies in this review demonstrated that medical clowning led to significantly reduced anxiety as measured by the Visual Analog-like scales. This suggests medical clowning is an effective and beneficial method for reducing anxiety in the pediatric patient undergoing medical intervention. Further studies should investigate the use of medical clowning with staff, guardians, and in various modalities.
7. **KEY WORDS:** clowning, anxiety