



Weighted Stuffed Animals and Dental Anxiety in Pediatric Patients: A Randomized Controlled Trial

Hussain Alfaikawi, Cheen Loo, Gerald Swee, Miranda Boynton, Sarah Pagni

Department of Pediatric Dentistry, School of Dental Medicine, Tufts University, Boston, MA, USA

Email: hussain.alfaikawi@tufts.edu

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Abstract

Background: Dental anxiety is a common barrier to effective care in pediatric patients. Deep touch pressure (DTP) interventions, such as weighted sensory tools, have demonstrated calming effects in various clinical settings, but their role in pediatric dentistry remains underexplored. **Methods:** This randomized controlled trial evaluated the effect of a weighted stuffed animal on anxiety and behavior in children aged 4 to 14 years receiving restorative dental treatment under nitrous oxide sedation. Seventy-seven participants were randomly assigned to an intervention group (received a 5-lb weighted stuffed animal) or a control group (no item provided). Behavioral outcomes were assessed using the Frankl Behavior Rating Scale, and post-treatment anxiety was measured using the Venham Picture Test (VPT). Statistical analyses were performed using the Mann-Whitney U test. **Results:** Children in the intervention group demonstrated significantly higher Frankl behavior scores (median = 4) than those in the control group (median = 3; $P < 0.001$), indicating greater cooperation. Self-reported anxiety was also significantly lower in the intervention group as measured by VPT scores ($P = 0.02$). No adverse events were reported. **Conclusions:** Use of a weighted stuffed animal during dental treatment was associated with improved behavioral cooperation and reduced anxiety in pediatric patients under nitrous oxide. This sensory-based intervention was well tolerated and easily integrated into routine care. **Practical Implications:** Weighted stuffed animals offer a noninvasive, low-cost adjunct to conventional behavior guidance techniques in pediatric dentistry. Incorporating DTP tools may enhance the patient experience and facilitate more successful clinical outcomes, particularly in anxious children.

Subject Areas

Dentistry, Pediatrics

Keywords

Dental Anxiety, Pediatric Dentistry, Deep Touch Pressure, Weighted Stuffed Animal, Behavior Management

1. Introduction

Dental anxiety in pediatric populations remains a significant barrier to effective and cooperative dental care. Estimates suggest that up to 20% of children experience clinically significant levels of dental fear and anxiety, often leading to avoidance, behavioral challenges, and compromised oral health outcomes [1]. Non-pharmacological interventions that reduce anxiety and promote cooperation during dental procedures are increasingly prioritized due to their safety, accessibility, and acceptability to both patients and caregivers.

One such intervention is Deep Touch Pressure (DTP) therapy, which involves the application of firm but gentle tactile stimulation, known to elicit calming effects through the modulation of the autonomic nervous system [2]. DTP is believed to reduce sympathetic activity, which is responsible for the body's stress response, while enhancing parasympathetic output, leading to physiological changes such as reduced heart rate, lower levels of stress hormones, and diminished subjective anxiety. Moreover, DTP is thought to stimulate the release of neurotransmitters like serotonin, which plays a crucial role in regulating mood and promoting feelings of well-being. This neurotransmitter elevation can further contribute to the calming effects experienced by individuals undergoing DTP therapy. Additionally, DTP provides significant proprioceptive input, which enhances body awareness and spatial orientation, creating a sense of safety and stability. The combined impact of these physiological and neurological responses underpins the use of weighted sensory tools—such as blankets, vests, and, more recently, stuffed animals—in various pediatric settings [3]. These tools leverage the principles of DTP to offer therapeutic benefits, promoting relaxation and comfort in children, especially during potentially stressful experiences like dental visits. By grounding the use of weighted sensory tools in the science of DTP, practitioners can better understand their efficacy in supporting children's emotional and sensory needs [3]-[5].

Weighted blankets, in particular, have demonstrated success in reducing anxiety and improving compliance in children during medical and dental procedures. Stein Duker *et al.* showed that the use of weighted blankets in pediatric dental settings was both feasible and highly acceptable to children, caregivers, and dental providers [6]. Similarly, DTP via papoose boards has shown physiological calming effects in children with special needs undergoing dental treatment [7]. These interventions leverage sensory integration strategies that align with established occupational therapy practices [8].

When the body experiences DTP through the weight of the blanket, there is an

increase in serotonin production, which can help elevate mood and mitigate feelings of anxiety and stress. Additionally, the calming effect of weighted blankets is linked to the reduction of cortisol, the primary stress hormone, which can lead to decreased feelings of tension and emotional distress [8]. The pressure exerted by the blanket also enhances proprioceptive feedback, allowing individuals to feel more grounded and secure in their environment. This, in turn, can create a sense of safety that is particularly valuable for children and individuals with sensory processing challenges. Consequently, by combining the soothing effects of increased serotonin with the reduction of cortisol levels, weighted blankets serve as an effective tool in promoting relaxation, improving sleep quality, and alleviating anxiety in various settings [9] [10].

The calming effects of DTP have also been well documented in populations with autism spectrum disorder (ASD), where devices such as weighted vests and inflatable compression garments improve regulation and reduce behavioral outbursts [9] [10]. While these devices have been validated in both clinical and home environments, there is limited research examining the application of weighted sensory tools designed for emotional comfort, such as weighted stuffed animals, in pediatric dentistry.

Weighted stuffed animals represent a unique, child-friendly DTP tool that may combine the physiological calming benefits of deep pressure with the emotional security of a comforting object. This dual mechanism has shown promise in other pediatric contexts but has yet to be rigorously studied within dental environments.

This randomized controlled trial aims to evaluate the effectiveness of weighted stuffed animals in reducing dental anxiety among pediatric patients undergoing restorative dental procedures under nitrous oxide sedation.

2. Methods

2.1. Study Design

This was a parallel group randomized controlled trial conducted at a university based dental pediatric department, from June 2023 to February 2024. The trial followed CONSORT guidelines.

2.2. Participants

Seventy-seven pediatric patients aged 4 to 14 years requiring restorative dental treatment under nitrous oxide sedation were enrolled. Inclusion criteria included ASA I or II status, need for restorative dental care, and capacity for assent with parental consent. Exclusion criteria were developmental disabilities, sensory integration disorders, behavioral disorders requiring pharmacologic management, contraindications to nitrous oxide, or patients who brought personal stuffed animals. Children with developmental or sensory disorders were excluded to participate in the study to create a homogenous sample, ensuring that the effects observed were attributable to the intervention rather than confounding variables associated with these disorders. By focusing on a neurotypical population, we aimed

to isolate and more accurately assess the impact of the weighted stuffed animals on dental anxiety, reducing the variability that could arise from differing sensory processing abilities or developmental challenges.

2.3. Randomization and Blinding

Patients were randomly assigned (1:1) using www.randomizer.org. Blinding of participants and providers was not feasible; however, outcome assessors were masked to allocation during data analysis.

2.4. Sample Size

A pilot study ($n = 10$) demonstrated a moderate effect size (Cohen's $d \approx 0.6$), which required 68 patients for 80% power ($\alpha = 0.05$). To account for attrition, 77 were enrolled.

2.5. Intervention

The experimental group received a 5-lb Harkla weighted stuffed animal during dental procedures. The control group received identical treatment without the weighted item. All procedures were conducted under standard care conditions with nitrous oxide and local anesthesia.

The choice of a 5-pound weight for the stuffed animal was based on findings from a pilot study, which indicated that this weight provided an optimal level of (DTP) for the target age group. Additionally, this weight aligns with standard recommendations suggesting that weighted items should generally be approximately 10% of the child's body weight to achieve the desired calming effects without causing discomfort.

2.6. Outcome Measures

The primary outcome was provider-rated behavior via the Frankl Behavior Rating Scale (**Figure 1**) The secondary outcome was patient-reported anxiety via the Venham Picture Test (VPT) (**Figure 2**).

2.7. Statistical Analysis

Using SPSS v29, Mann-Whitney U tests were conducted for between-group comparisons. Statistical significance was defined as $P < 0.05$.

Rating	Attitude	Definition
1	DEFINITELY NEGATIVE	Refusal of treatment, crying forecfully, fearful or anyother overt evidence of extreme negativism
2	NEGATIVE	Relucatan to accept, uncooperative, some evidenvce of negative attitude but not pronounced, i.e / sullen
3	POSITIVE	Acceptarve of treatmnet; at times cautious, willingness to comply with the dentist, at times with reservation but patinet follows the dentist's directions cooperatively.
4	DEFINITELY POSITIVE	Good rapport with the dentist, interesyed in the dental procedures, laughing and enjoying the situation.

Figure 1. Frankl behavior rating scale.

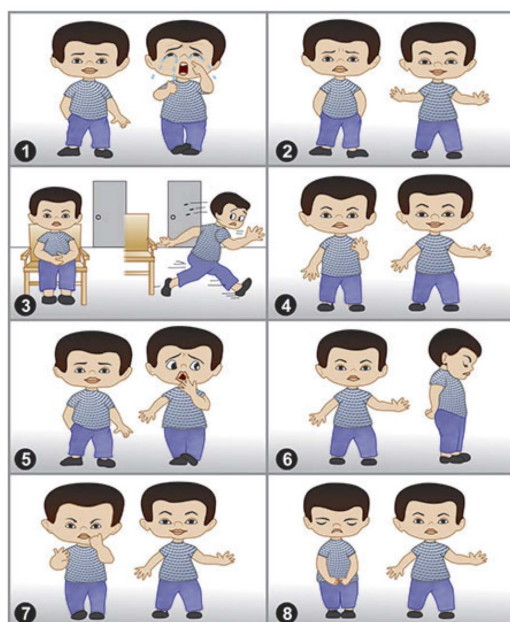


Figure 2. The Venham picture test.

3. Results

A total of 77 pediatric patients aged 4 to 14 years were enrolled and randomized into two groups: the experimental group ($n = 39$) received a 5-lb weighted stuffed animal during restorative dental treatment with nitrous oxide, while the control group ($n = 38$) received treatment without the weighted stuffed animal. All procedures were completed by pediatric dental residents at the university-based pediatric dental clinic.

Analysis of behavioral outcomes revealed a statistically significant difference in Frankl behavior scores between the two groups. The median Frankl score in the control group was 3, compared to a median score of 4 in the intervention group ($P < 0.001$, Mann-Whitney U test), indicating more cooperative behavior in the group using the weighted stuffed animal (**Figure 3**).

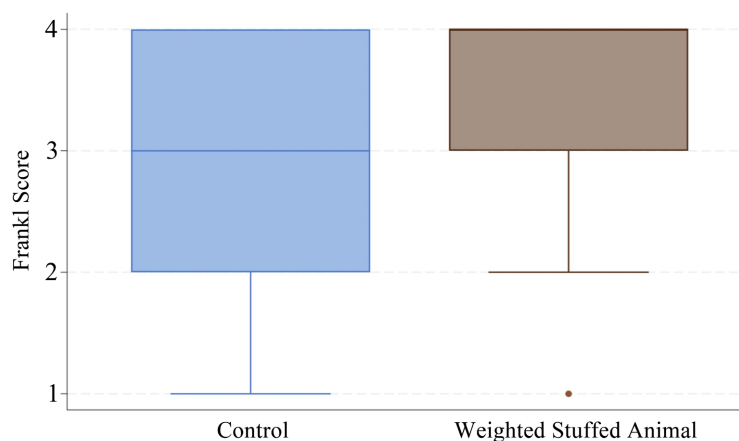


Figure 3. Box plots of the Frankl scores between the control and study groups ($P < 0.001$).

Self-reported anxiety, measured using the Venham Picture Test (VPT), also demonstrated a significant difference between groups. The intervention group had lower anxiety scores compared to the control group ($P = 0.02$, Mann-Whitney U test), suggesting a positive effect of the weighted stuffed animal on patient-reported anxiety levels (Figure 4).

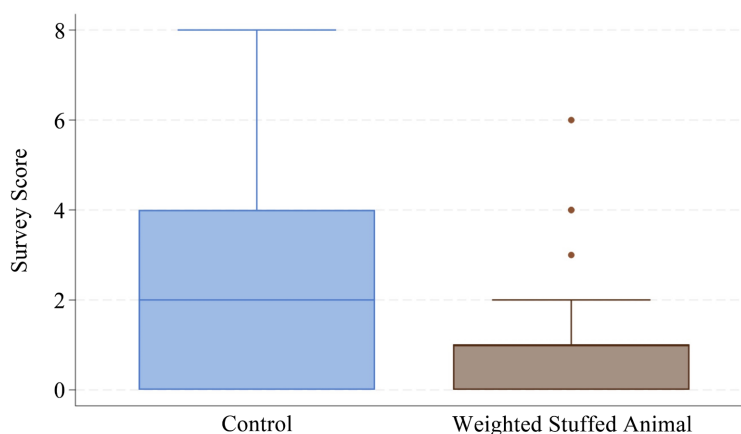


Figure 4. Box plots of the self-survey (Venham Picture Test) scores between the control and study groups ($P = 0.02$).

Baseline characteristics were similar between groups. The mean age was 7.4 years (SD = 2.5) in the control group and 7.1 years (SD = 1.9) in the intervention group, with no significant difference between groups ($P > 0.05$). Gender distribution was also comparable, with 25 females and 16 males in the control group, and 20 females and 16 males in the intervention group.

Dental procedures included resin composite restorations, stainless steel crowns (SSCs), and glass ionomer restorations. Extractions were excluded from the study due to their potentially higher anxiety-provoking nature.

There were no adverse events or patient withdrawals during the study period.

4. Discussion

This randomized controlled trial is the first to our knowledge to investigate the effectiveness of a weighted stuffed animal as a deep touch pressure (DTP) intervention for reducing dental anxiety and improving behavioral compliance in pediatric dental patients undergoing restorative treatment under nitrous oxide. The findings suggest that the use of a 5-pound weighted stuffed animal significantly improved both clinician-rated behavior and self-reported anxiety, as demonstrated by higher Frankl scores and lower Venham Picture Test (VPT) scores, respectively. These findings support the integration of sensory-based tools in pediatric dentistry to enhance patient comfort and cooperation.

The observed improvement in patient behavior aligns with prior studies demonstrating the calming and regulatory effects of deep touch pressure stimulation. DTP has been shown to reduce sympathetic arousal and increase parasymp-

pathetic tone, resulting in decreased anxiety and improved emotional regulation [1]-[3]. The weighted stuffed animal in this study likely mimicked the physiological mechanism of weighted blankets, which are well-documented to promote relaxation by applying pressure to pressure receptors under the skin [4].

Our findings echo those of Stein Duker *et al.*, who found that weighted blankets were feasible, acceptable, and perceived as calming during routine pediatric dental care [5]. Similarly, Chen *et al.* demonstrated that the application of DTP via papoose boards modulated autonomic nervous system activity and promoted parasympathetic dominance in patients with special needs undergoing dental treatment [6]. These physiologic mechanisms are particularly relevant in children who often present with anticipatory anxiety prior to dental procedures.

Moreover, the emotional and behavioral benefits of DTP-based devices have been extensively documented in pediatric populations with sensory sensitivities and neurodevelopmental disorders. Devices such as weighted vests and inflatable compression garments have demonstrated efficacy in improving behavior in children with autism spectrum disorder (ASD) [7] [8]. Although children with developmental disorders were excluded from this study, the general pediatric population may still benefit from the calming effects of DTP as a form of sensory modulation, especially in anxiety-provoking environments like dental clinics.

The use of a weighted stuffed animal, specifically, adds a novel emotional dimension beyond the physical weight application. Unlike traditional weighted blankets or vests, stuffed animals offer psychological comfort through familiar, playful, and nurturing associations. This may further reinforce positive coping and reduce fear, particularly in younger children. As shown in other studies, combining sensory comfort with emotionally positive stimuli (e.g., weighted toys or comfort objects) can have synergistic effects in anxiety reduction [9] [10].

Self-reported anxiety was significantly lower in the intervention group, as measured by the VPT. These results are consistent with findings from adult medical settings, where weighted blankets have been used to alleviate anxiety during chemotherapy and inpatient treatments [11]-[13]. The anxiety-reducing effects of weighted blankets have also been associated with improved sleep, emotional stability, and overall stress reduction in children and adults [14] [15]. Our findings contribute to this growing body of evidence by confirming similar benefits in an acute dental care setting.

Importantly, this intervention is non-invasive, low-cost, and well-tolerated, with no reported adverse events. This makes it highly attractive for pediatric dental practices seeking to minimize pharmacologic sedation or enhance behavioral management strategies. Notably, the device used in this study required minimal training, no maintenance, and did not interfere with clinical care delivery.

Despite these strengths, this study is not without limitations. Blinding of participants and providers was not feasible due to the visible nature of the intervention, which may have introduced observer bias. However, behavior ratings were recorded by clinicians masked to group allocation during analysis, reducing po-

tential bias in outcome measurement. Additionally, the exclusion of children with sensory disorders may limit generalizability to special needs populations, though this also allowed for a more homogenous analysis of effects in typical pediatric patients.

It is important to acknowledge the potential confounding effect of nitrous oxide sedation, which is an established anxiolytic. The observed effects of the weighted stuffed animals should be interpreted within the context of their use alongside nitrous oxide, as this interaction may influence the overall efficacy of the intervention. While the weighted animals were found to reduce dental anxiety, the concurrent administration of nitrous oxide could also contribute to the participants' sense of calm and comfort. This overlap underscores the need for further investigation to disentangle the specific contributions of each modality and to understand how they may interact to enhance the overall therapeutic effect in managing anxiety during dental procedures.

The positive effects observed may be partly due to the unique appeal of the weighted stuffed animals during a single dental visit. Future studies should investigate whether the anxiolytic benefits are sustained over multiple appointments, determining if the initial comfort and reduced anxiety continue as children become accustomed to their use. This exploration could provide valuable insights into the long-term effectiveness of the intervention in pediatric dental care.

Future studies should explore the long-term effects of weighted sensory tools on dental anxiety, their utility in various clinical contexts (e.g., orthodontics, hygiene visits), and the underlying mechanisms via physiological monitoring (e.g., heart rate variability). Additionally, qualitative feedback from patients and caregivers may further inform user experience and intervention acceptability.

5. Conclusion

The results of this randomized controlled trial suggest that the use of weighted stuffed animals during restorative dental treatment under nitrous oxide sedation significantly reduces anxiety and enhances cooperative behavior in pediatric patients. This non-invasive, low-cost sensory-based intervention offers a novel adjunctive strategy to support behavior guidance in children with dental anxiety. By incorporating principles of deep touch pressure, weighted stuffed animals may help pediatric patients feel more secure and calm during dental procedures, ultimately improving their treatment experience. Further research is warranted to evaluate the long-term impact of such interventions across different clinical settings and among children with special health care needs.

6. Clinical Significance

This study provides evidence supporting the use of weighted stuffed animals as a simple, noninvasive adjunct to conventional behavior guidance strategies for pediatric dental patients. Incorporating weighted sensory tools during treatment—particularly with nitrous oxide—may help reduce anxiety and improve behavioral

outcomes in children. This approach has the potential to enhance patient cooperation and create a more positive dental experience, especially for those with heightened dental anxiety.

A key consideration for practitioners is the adherence to infection control protocols when using reusable sensory tools, such as weighted stuffed animals, in a clinical setting. Ensuring that these items are appropriately sanitized between uses is crucial for maintaining a safe environment for all patients, thereby maximizing the therapeutic benefits of the intervention while minimizing any risk of cross-contamination.

Clinical Relevance Statement

This study explores a non-pharmacologic, sensory-based intervention using weighted stuffed animals to reduce dental anxiety in pediatric patients, potentially enhancing cooperation and comfort during dental visits.

Conflicts of Interest

The authors declare no conflicts of interest.

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