

**THE EFFECTS OF THERAPY DOG INTERVENTION ON DISTRESS IN
ADULT PATIENTS UNDERGOING DENTAL PROCEDURES:
A PILOT STUDY**

by

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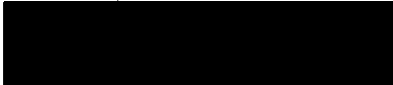
MASTER'S THESIS


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2019

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ABSTRACT

THE EFFECTS OF THERAPY DOG INTERVENTION ON DISTRESS IN ADULT PATIENTS UNDERGOING DENTAL PROCEDURES: A PILOT STUDY

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M.S., COMPREHENSIVE DENTISTRY, 2019

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INTRODUCTION: Dental anxiety affects an estimated 14-34 million Americans. Fearful patients may voluntarily avoid dental treatment, which can lead to otherwise preventable oral disease. Currently, a variety of treatment is available for aiding patients with dental anxiety, including psychological and pharmaceutical therapies, each with associated costs and risks. Recently, there has been an increase in the use of therapy dogs to ease anxious patients in various settings. Studies have demonstrated the psychological benefits of therapy dogs in medical settings. However, there is not any available research on the impact of therapy dogs on adult patients with dental anxiety.

PURPOSE: This pilot study assessed the feasibility and efficacy of reducing dental anxiety in adult patients by using a therapy dog intervention.

METHODS: Adult patients reporting dental anxiety were invited to participate in this study. After consent, participants were randomized into a therapy dog group (DOG) or standard care (SC) control group. A ten-minute intervention with a therapy dog occurred at the first two dental treatments for participants in the DOG group. Study outcomes

included psychological (e.g., anxiety) and physiological (e.g., heart rate variability) assessments.

RESULTS: Preliminary result for this ongoing study (N=15, 10 DOG, 5 Control) show that patients are enthusiastic about using therapy dogs to manage dental anxiety. All participants reported significant dental anxiety at baseline. There was no significant decrease in dental anxiety or generalized anxiety in either group (p 's > 0.05), however there was significant difference in state anxiety at the second visit, with the DOG group reporting less anxiety ($p < 0.05$). All participants reported a significant decrease in depressive symptoms ($p < 0.05$). Patients in the DOG condition reported being satisfied with the intervention.

CONCLUSIONS: Therapy dog intervention for adults with dental anxiety appears to be effective in helping patients adhere to appointments and may reduce state anxiety experienced during dental treatment. The therapy dog intervention appears to be well-received and may reduce the use of standard pharmacological interventions such as anxiolytics.

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2. SC- Standard Care	ii
3. IDAF– Index of Dental Anxiety and Fear	4
4. NPDS- Naval Postgraduate Dental School	11
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REVIEW OF THE LITERATURE

Chapter 1

Prevalence and Impact of Dental Anxiety

Dental anxiety is the second most commonly reported fear, behind only the fear of public speaking, based on a survey of adult Americans (Malamed, 2018). In a separate 2014 survey, 16% of “affluent Americans” regarded dentistry as a common fear (Merrill Edge, 2014). Approximately 6-14% of the U.S. population, or in absolute terms, 14-34 million people, avoid dental treatment due to anxiety (Malamed, 2018). The prevalence of dental anxiety is not unique to the United States. For example, Armfield found that dental anxiety affects approximately one in six Australians (Armfield, 2013). A cross cultural study of dental anxiety in Chinese and Danish patients reported prevalence of 30% and 15%, respectively (Carter, 2014).

Dental anxiety has a direct impact to patients and providers alike, with associated costs. First, anxious patients will voluntarily avoid dental treatment, which may lead to otherwise preventable oral disease and infection. Further, it has been reported that oral health has a direct influence on the quality of life (Beaton, 2014), thus the quality of life for the dentally anxious patient is potentially at risk as well. Additionally, anxious patients have been shown to cancel or fail to report to a scheduled dental appointment, which represents a financial burden to dental practices. Furthermore, the dentally anxious patients are often difficult to treat and require additional clinical time. These patients often present with behavioral problems resulting in stressful interactions for both

the patient and provider (Armfield, 2013). Patients that delay treatment due to dental anxiety may allow small dental problems to develop into larger ones, with more aggressive and costly treatment, perhaps even losing teeth. This can lead to feelings of self-consciousness. Furthermore, parents that suffer from dental anxiety may avoid even taking their children to the dentist, which predisposes their children to dental issues (Karnad, 2015).

Etiology

The cause of dental anxiety has been studied and many processes are known to affect its development, including behavioral, cognitive factors, and genetic susceptibility (Carter, 2014). Clinicians can better treat patients by better understanding the causes of dental anxiety.

Behavioral causes are widely studied and known to have significant impact on the development of dental anxiety, as a previous traumatic dental experience could have a lasting impact on a patient. Classic conditioning theory, which is estimated to be the most common pathway to the development of dental anxiety, occurs when a patient's personal past experiences result in the expectations of future events. According to Beaton, patients that reported a stressful dental experience were more than twice as likely to also experience high dental anxiety (Beaton, 2014). In a recent review, Carter found a strong direct association between the severity of trauma-related symptoms and the patient's level of dental anxiety (Carter, 2014). To a broader extent, it has been shown that distressing experiences outside of dentistry, can cause dental anxiety. Humphris and King reported that victims of sexual assault reported dental anxiety at a rate 2.5 times

greater than study participants that were not sexually assaulted (Humphris, 2011). Dental anxiety can also have its basis in indirect vicarious learning. This is essentially learning based on modeled behavior. This occurs when a person models the behavior of family members, friends, or even the media. In a recent study, Beaton confirmed that a mother or father's history of dental anxiety was a positive predictor of dental fear and anxiety in their children (Beaton, 2014)

Researchers have suggested a cognitive explanation regarding the etiology of dental anxiety. The term cognition here refers to the mental processing of information linked to what the individual experiences and his or her perceptions of that experience filtered through previous learning and life events (Armfield, 2010). Armfield describes a strong association between cognitive vulnerability perceptions (e.g., lack of control, unpredictability, danger, and disgustingness) and the development of dental fear. Specifically, he theorizes that a patient's perception of a potential stimulus is the critical factor, more so than the particular experience (Armfield, 2010).

Finally, it has been suggested in recent studies that a genetic etiology may exist with regard to predisposition to dental anxiety. Studies indicated that it doesn't appear that patients with dental anxiety directly inherit the anxiety issue, however, there may be a genetic predisposition to other etiologies that could contribute to the development of the anxiety. In a longitudinal study of Swedish twins, research indicated that a heritability component may exist. The researchers in this study found a genetic component associated with dental fear/anxiety which was also more likely to be inherited by girls than boys. (Ray, 2010). In other research, studies indicate that individuals with predispositions to co-morbid mental health issues, such as depression, may be related to

increased likelihood that an individual may have dental anxiety. In particular, Locker (2001) noted that highly anxious patients were significantly more likely to have additional diagnosis of conduct disorder, agoraphobia, social phobia, simple phobia or alcohol dependence. Additionally, patients with dental anxiety and co-morbid psychological conditions were more likely to maintain their anxiety over time (Locker, 2001).

Assessment

Various self-report measures have been created as screening tools for dental anxiety. Some are well studied in the literature, establishing the measures as simple and effective tools to assess dental anxiety. Such an assessment is the highly studied Index of Dental Anxiety and Fear-4C (IDAF-4C), which was the survey utilized in the present study. The IDAF-4C is a survey that utilizes three modules to measure the components of dental fear, dental phobia, and potential anxiety producing stimuli. The components of dental fear include emotional, behavioral, cognitive, and physiological components. Research on the IDAF-4C demonstrates the survey is highly reliable. Norms have been established for numerous populations (Armfield, 2010). Therefore, the IDAF can be used as an assessment of an individuals' level of dental anxiety and make provisional diagnosis of dental phobia. Additionally, the Modified Dental Anxiety Scale (MDAS) is a simple questionnaire that produces reliable screening, and has a researched set of norms to make it a useful tool for practicing dentists. It is a simple series of five questions, which makes application very easy. But, the MDAS fails to provide level of information that the IDAF-4C provides, including relevant stimuli for patients (Humpris, 2009).

While self-report measures are useful and the ones discussed above have demonstrated good psychometric validity and reliability, responses on these measures are filtered by the individual perceptions and biases of the person. More recently, the addition of the concurrent assessment of physiological reactivity has added an additional dimension to the measurement of anxiety before and during stressful stimuli. This physiological assessment often includes the measurement of the heart rate variability (HRV). This physiological index is a measure of the time between each heartbeat, measured in milliseconds (ms) over a specific period of time (Task Force, 1996). Heart rate variability has been shown to be a simple and noninvasive measure of the autonomic nervous system. When stressed, a patient will demonstrate decreased HRV, which is an indication of increased sympathetic activity. When patients are relaxed, HRV will increase, indicating increased parasympathetic activity. Studies have demonstrated a predictive link between depressed HRV and acute myocardial infarction (Task Force, 1996), chronic pain (Schmidt & Carlson, 2009) and affective distress (Johnsen, Thayer, 2003). Specifically, the Task Force of the European Society of Cardiology and The North American Society of Pacing and Electrophysiology stated that HRV can be used for risk stratification following myocardial infarction, as well as consistently observing low HRV in heart failure patients. While the gold standard to measure HRV is analysis of an electrocardiogram, there are many commercially available products available to determine HRV, including the Firstbeat Bodyguard which is used in the present study (Task Force, 1996).

Treatment Options

A wide range of treatment options exist for managing patients with dental anxiety. There is not a “one size-fits-all” solution, as each intervention approach carries associated benefits and risks. Currently available options include hypnosis, cognitive behavioral therapy (CBT), and pharmacological solutions such as anxiolysis, intravenous conscious sedation (IVCS), and general anesthesia (GA) (Malamed, 2018).

Cognitive behavioral therapy (CBT) requires treatment by a trained clinical psychologist to essentially restructure a patient’s negative thoughts, as well as to increase the patient’s control over these cognitions. This can be potentially be a lengthy process of identifying misperceptions and “catastrophic thoughts” related to the individual patient’s dental fears. These misperceptions are challenged and replaced with more rational thoughts (Armfield, 2013). While this is minimally invasive and low risk, CBT represents a considerable time and financial commitment from the patient and is not a certainty for success. Additionally, Karnad (2105) reported that, despite the benefits of CBT, there is an “availability barrier” for many patients due to access to qualified clinical psychologists.

Hypnosis is another non-pharmacologic method utilized to decrease dental anxiety. Hypnosis is an interactive process between the provider and the patient. The provider, or hypnotist, influences the patient’s perceptions allowing the patient to enter a trance-like state where feelings and reactions can be altered and managed through hypnotic suggestions. While hypnotized, a patient’s attention is shifted to enter a mental state where they are less affected by external stimulation. In this manner, patients can better tolerate dental procedures. Hypnosis has been used to better understand a patient’s source of dental anxiety and their feelings about future appointments (Armfield,

2013). Hypnosis, which requires additional training, has been shown to be helpful for some patients, but certainly not all (Karnad, 2015).

Minimal sedation, which is also known as “anxiolysis,” utilizes pharmacological agents to depress the central nervous system for patients with mild to moderate anxiety. In clinical practice, benzodiazepines taken via the oral route, such as lorazepam, midazolam, and diazepam, are used alone, or in addition to nitrous oxide, to create a minimally sedated state for patients. In this state, patients maintain their airway and are typically responsive to verbal direction (Lewandowski, 2016). Anxiolysis requires less equipment and monitoring than IVCS or GA, and is of lower cost to utilize. Additionally, it can provide adequate sedation for many patients, without the risks of deeper levels of sedation. However, oral anxiolytic agents have variable onset and unpredictable levels of sedation that can’t be titrated like an IV or GA agent. Therefore, it is possible to under or over sedate a patient with oral anxiolytics. Additionally, with the use of any pharmacologic agent, there is a risk of an untoward reaction, such as an allergy. Depending on the clinical practice, additional licensure or credentials may be required (Karnad, 2015).

For those patients with moderate to severe anxiety, a deeper level of sedation may be required. Intravenous conscious sedation (IVCS) is also a drug-induced depression of the central nervous system. Depending on the level of sedation, the patients may or may not be able to purposefully respond to verbal commands. They are, however, able to maintain their own airway. IVCS, which is highly effective, utilizes IV benzodiazepines and opioids to achieve this effect (Malamed, 2018). Clearly, with deeper levels of sedation, there is increased risk when compared to oral anxiolysis or non-

pharmacological methods. Additionally, the use of opioids must be carefully considered for individual patients, as there is a potential abuse risk (Lewandowski, 2016).

Periodically, a patient has anxiety beyond what can be adequately managed in an outpatient setting. These patients can be managed with general anesthesia (GA), which utilizes anesthetic agents that place a patient in a non-arousable, drug-induced state of unconsciousness (Lewandowski, 2016). The 2012 American Dental Association Policy Statement: The Use of Sedation and General Anesthesia by Dentists describes GA as “complete relief from both anxiety and pain.” While this is the most effective method for patients with dental anxiety to complete their care, it is also the solution with the most risk and costs (Karnad, 2015). Utilizing GA requires a significant amount of training, additional licensure and inventory, such as recording, monitoring, and emergency care equipment. The ADA encourages clinicians to utilize GA for only patients that require it. Lastly, practitioners should use discretion employing these drugs with abuse potential (ADA, 2012). In fact, Newton (2012) cautions clinicians to be aware that patients with dental anxiety, as well as the general public, do not view pharmacological approaches positively, when other non-pharmacological approaches are available such as CBT.

Animal Assisted Therapy

The bond between animals and humans has evolved over time. In early times, domestic animals were largely a source of economic support which evolved to include companionship. Recently, Creagan (2015) discusses the overwhelming anecdotal evidence that supports the healing power of this relationship. Animals have increasingly been involved in supporting various types of patient care. Animal-assisted therapy

(AAT) is used as a complementary intervention concurrent with other modalities to provide therapeutic comfort (usually with specially trained dogs) to patients in a variety of health care settings (Marcus, 2013). Therapy dogs have also been successfully used with pediatric and adolescent patients in a variety of medical settings (McCracken, 2016).

Certified therapy dogs are specially trained to be safe and non-disruptive and are veterinarian certified (Marcus 2013). In medical settings, all dogs have an assigned dog handler that trains with the dog. During a therapy dog visit, a patient typically interacts with the therapy dog for 10-15 minutes per session. These interactions can include playing with, petting, cuddling, and giving the dog snacks. The dog handler is present throughout the interaction to answer any questions, as well as monitor the dog.

Various theories exist to explain the therapeutic effects of animal assisted therapy in physiological terms. Studies have identified physiologic changes in patients interacting with therapy dogs reporting stress reduction, pain reduction, and mood elevation. Specifically, studies have demonstrated that patients' epinephrine and norepinephrine, which are endogenous stress hormones, decrease following dog therapy visits. Additionally, endorphin levels have been demonstrated to increase during dog visits (Odendaal, 2003). Oxytocin, a hormone associated with social bonding, anti-stress effects, and elevated pain threshold, was shown to increase following dog interactions (Miller, 2009). These biologic changes have produced measurable changes to patient physiology. For example, in a sample of 18 healthy adult patients, the mean arterial blood pressure was shown to be significantly reduced after therapy dog interaction from 87.6mmHg to 84.4mmHg. (Odendaal, 2003). Additionally, 178 patients receiving chemotherapy for a variety of cancers demonstrated a statistically significant 6%

increase in arterial oxygen saturation when their chemotherapy treatment was accompanied by pet therapy, as compared to a nonsignificant 4% decrease for control patients. The dog interaction consisted of three phases of 20 minutes each. During the first 20 minutes, the patient observed the trainer working with the dog. During the second 20 minutes, the patient could play with the dog. For the final 20 minutes, the patient could feed and hold the dog (Orlandi M, 2007).

Clearly, AAT offers physiologic benefits for patients, particularly those patients with anxiety, depression, and dealing with pain. That said, studies indicate that AAT should be a complement to their medical plan. There are limitations associated with the use of animals in therapy. Of note, patients may have animal phobias, allergies, and stress associated with the presence of an animal, based on their individual history and situation. Additionally, it is important to have a realistic perspective of their potential benefit. Working with, or owning a trained therapy dog will not cure disease or chronic conditions (Creagan, 2015), but studies demonstrate a strong association between therapy dog interactions and improved psychological distress and physiological reactivity (Fiocca, 2017). Reduced distress and reactivity are strongly associated with reduced symptom severity and improved health outcomes (Schniedermann, 2005).

During a thorough review literature, no studies were identified that used AAT with adult patients struggling with dental anxiety or in a dental setting. The aims of the present research is to determine treatment adherence and feasibility of the use of a therapy dog intervention in the management of dental anxiety. Additionally, the secondary aim of the present study is to determine if there is any change in psychological

status (anxiety, depression) before and after treatment. Furthermore, we will utilize HRV to determine any change in physiologic characteristics following AAT intervention.

I think you should bullet, or number your aims to match the data analyses that describes how each aim will be tested. Page 24.

Materials and Methods

Participants: Study participants were patients enrolled in the Naval Postgraduate Dental School (NPDS) Comprehensive Dentistry program, a two-year advanced education in general dentistry (AEGD) training program, or enrolled in the one-year AEGD program. Eligible participants required a combination of endodontic therapy, periodontal treatment, oral surgery, prosthodontic or other restorative procedures as dictated by each patient's individual treatment plan. These patients required multiple treatment sessions and were treated by one of the residents in the Comprehensive Dentistry or AEGD training programs.

Program patient coordinator identified study participants during the initial pre-treatment screening. Individuals who checked the box for and reported that they have "nervousness" in the Dental Health Questionnaire (DHQ) were identified as potential study participants. During the pre-treatment screening visit, the patient was screened to determine if study criteria are met including the dog screener (see Patient Screening Procedures form). If the potential study patient met all criteria and was interested in study participation, Informed Consent was reviewed and signed by the study participant.

Inclusion criteria: age \geq 18yrs, with dental anxiety, generalized or situational anxiety, and required at least 3 separate dental appointments.

Exclusion criteria: fear of dogs, dislike of dogs, severe dog allergy, pregnant or breast-feeding women, history of schizophrenia or other chronic psychotic disorder, and acute psychiatric symptoms that impair ability to function in non-psychiatric setting.

Study participants were randomly assigned to the intervention (DOG) group and the Standard Care (SC) group. The SC group was a wait-list control condition and all participants in the SC group had the opportunity to interact with the therapy dogs after two initial dental treatment sessions.

Study Procedures (see Figure 1 and Study Plan in appendix)

Written informed consent was obtained from eligible patients during the patient screening visit in accordance with IRB/HIPAA guidelines. After consent and the Demographics and Health History Questionnaire were completed, each participant completed the Index of Dental Anxiety and Fear-4C (IDAF-4C) to get a baseline assessment of dental anxiety and fear. Each participant was assigned to either a one or two year AEGD resident and scheduled to return for their first appointment with the assigned resident provider.

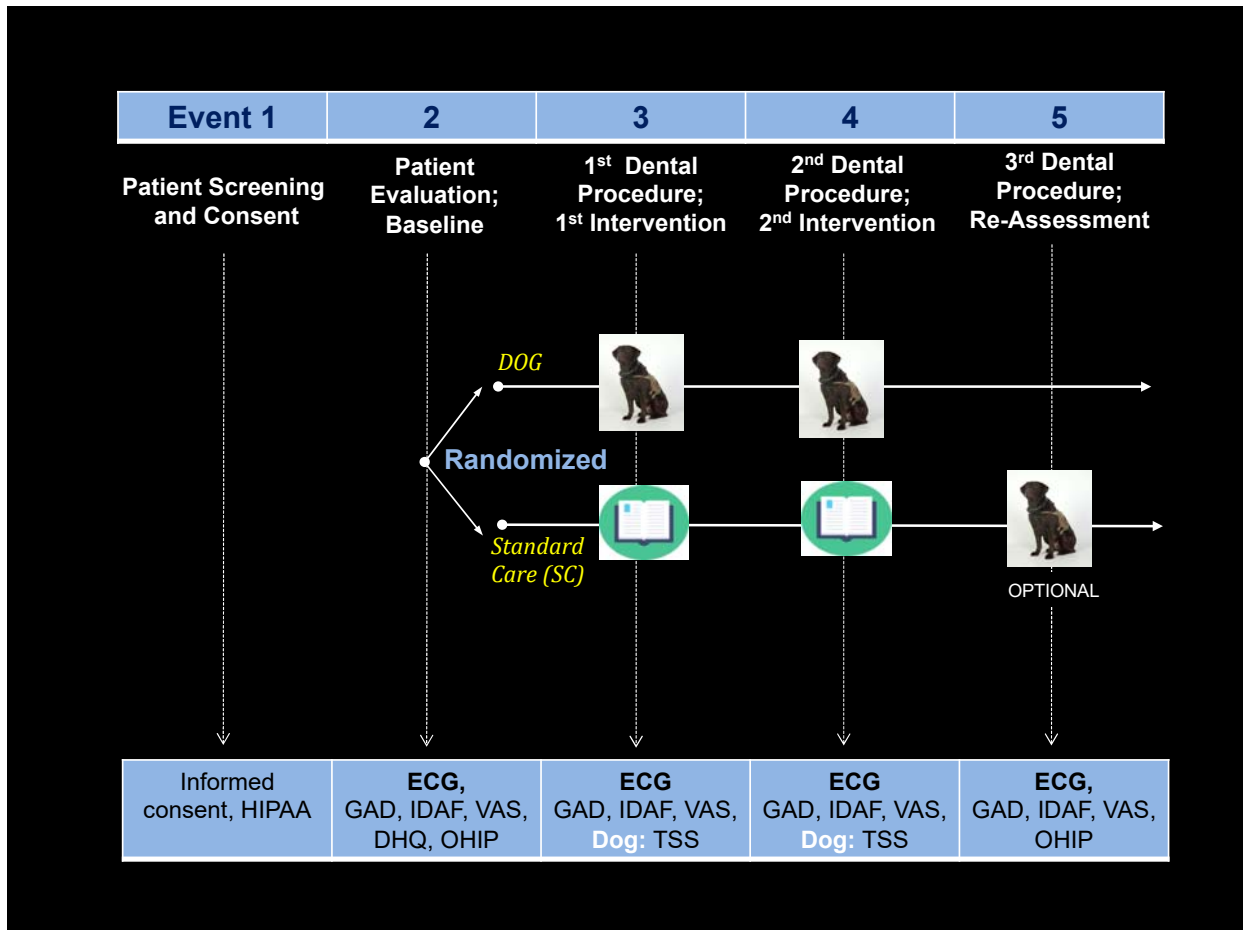
The intervention sessions took place at the first two dental treatment sessions. All study participants completed self-report measures in the clinic waiting area prior to

treatment. Once the participant was brought back to the operatory, the Firstbeat ECG device was attached. Participants in the DOG group spent 10 minutes with a treatment dog accompanied by study personnel and the dog handler prior to initiation of dental treatment. Participants assigned to the SC group spent 10 minutes in the operatory quietly resting (reading magazines, etc.) prior to the initiation of dental treatment. Following the 10 minute period (for both groups), each participant completed the Index of Dental Anxiety and Fear (IDAF-4C). Each participant also completed the study Visual Analog Scale (VAS) (measuring anxiety and comfort level on a visual-analog scale) at the end of each dental treatment appointment. At the end of both intervention visits, participants in the DOG group also completed the Therapy Satisfaction Scale (TSS). Any miscellaneous provider notes or notes from the dog handlers were documented. Provider notes included topical administered, local anesthesia administered, the number of local anesthetic cartridges used (if local anesthesia is administered), bite block or isolation put in place, or treatment initiated. Handler notes included types of interactions between the participant and the dog (e.g., petting, hugging, speaking, treats used).

The final study session (Intervention visit 3) for participants in the DOG group began with the completion of study self-report measures in the clinic waiting area. Once the participant was brought back to the operatory, the Firstbeat ECG device was attached. Prior to the start of dental procedures, the participant completed the IDAF-4C. After completion of all dental procedures, the participant completed the VAS and the Therapy Satisfaction Scale. At this point, the participant was released from the study and thanked for participating. Any miscellaneous provider notes were documented.

Participants in the SC group were given the opportunity to interact with the therapy dogs at their third intervention visit. The final study session for participants in the SC group began with the completion of study self-report measures in the clinic waiting area. Once the participant was brought back to the operatory, the Firstbeat ECG device was attached. SC group participants interacted with the therapy dog for 10 minutes. Prior to the start of dental procedures, the participant also completed the IDAF-4C. After completion of all dental procedures, the participant completed the VAS and the Therapy Satisfaction Scale. At this point, the participant was released from the study and thanked for participating. Any miscellaneous provider and handler notes were documented.

Figure 1. Recruitment, Intervention and Assessment Timeline



Event Details.

1. Patients were screened for the study.
 - a. Patients who met inclusion and exclusion criteria were offered to complete consent.
 - b. Screening included questions to assess for fear of dogs, dislike of dogs, and dog allergies.

2. Participants met with their perspective residents to develop treatment plan and completed baseline assessment.
 - a. Baseline assessment included self-report measures and resting ECG using Firstbeat Bodyguard devices.
 - b. After assessment, participants were randomly assigned to DOG or SC (Standard Care) groups.
3. Participants in the DOG group were introduced to the dog and spent 10 minutes with dog in operatory prior to dental treatment.
 - a. Participants in both groups completed self-report measures before and after intervention and after dental treatment.
4. Participants in the DOG group had second exposure to dog prior to dental treatment. Assessments for both groups were identical to #3.
5. At third appointment, all participants repeated the baseline assessment. Participants in the SC group were provided with the dog intervention.

Intervention details

DOG group. Study participants assigned to the DOG group spent 10 minutes with the dog, the dog handler, and study personnel in the operatory prior to the start of any dental procedures during the two study session visits. During the intervention, the handler was allowed to give the participant dog treats that the participant may give to the dog to facilitate an interaction. The dog handler did not interact with the patient any further to avoid any confounding interactions.

When a study patient in the DOG group was scheduled for a treatment session, the therapy dog coordinator was informed to ensure that a dog and handler were available for the schedule appointment. One therapy dog was allowed to be in the room at a time. This study had access to six therapy dogs, therefore up to six participants randomized to the intervention group would be allowed to be seen concurrently.

The instructions to the dog handler were to wait and standby for the scheduled appointment. When the participant was brought back to the operatory after completing the self-report measures and had the Firstbeat device attached, the handler arrived with the therapy dog and introduced him or herself and the therapy dog. Due to limited space in the operatory, each handler stood at the foot of the operatory chair. At the end of the ten minutes, the dog handler reported what specific type of interaction occurred between the participant and therapy dog. Due to different personalities between individual dogs, which led to slight variations in interactions between the patient and dog, the specific therapy dog used at each treatment session was recorded.

The instructions given to each patient in the dog condition by the dog handler were:

“You can sit with, pet, feed, hug, kiss, and interact with the dog as you like for the next 10 minutes. When the 10 minutes are up, we will start your dental treatment.”

Prior to starting dental treatment, and after the 10 minute visit with the therapy dog, each participant completed the IDAF-4C to assess current dental fear/anxiety.

SC group (wait list control). Study participants assigned to the SC group spent 10 minutes in the operatory resting and/or reading magazines or books. Once the 10 minute resting time was up, dental treatment began per usual care. At Event 5, the SC group participants had an opportunity to interact with a therapy dog, following the same procedures as the DOG group participants do in Events 3 and 4.

Psychological and Physiological Assessment

Assessments for this study included self-report measures and heart rate. To record heart rate (electrocardiograph or ECG) data, Bodyguard (FirstBeat Technologies, LTD.) was used. The Bodyguard is a two lead portable heart rate recording device. The device was attached to the study participant at the start of each study assessment after the participant completed self-report measures. The Firstbeat device recorded ECG data from the start of the DOG intervention (or SC group resting period) to the end of the dental treatment visit.

Self-report measures

All patients completed the following self-report measures. Please see Table 1 for details on frequency of each self-report measure. All self-report measures were included in the Appendix.

Pre-consent screening. At screening and prior to signing consent, all potential participants were screened for study inclusion/exclusion criteria. Screening included reviewing the ‘nervousness’ box on the Dental Health Questionnaire and verbally inquiring about dental anxiety at the screening visit. Potential participants were also asked about the presence of fear of dogs, dislike of dogs, and dog allergy. If the answer to any of these questions was yes, then the individual would not be eligible for study participation. See the Patient Screening Procedures sheet for details.

Demographics and Health History Questionnaire. All participants completed a brief demographics and health history questionnaire after study enrollment. Information recorded here includes ethnicity, race, marital status, job status, as well as questions about dental and medical history, current medications, and current use of non-prescription supplements.

Index of Dental Anxiety and Dental Fear (IDAF-4C). The IDAF-4C (Armfield, 2010, 2011) is a 23-item measure that contains three modules assessing dental anxiety, phobia, fear, and feared dental stimuli. This measure also assesses emotional, behavioral, physiological, and cognitive components of the anxiety and fear response. All items are on a 5-point Likert scale. The IDAF-4C provides a total score and four subscale scores

(cognitive, physiological, behavioral, and emotional). The IDAF-4C has demonstrated good internal consistency, validity, and test-retest reliability (Armfield, 2010, 2011).

Oral Health Impact Profile short form (OHIP-14). The OHIP-14 (Slade, 1997) is a 14-item measure of the social and psychological impact of oral health on general well-being. It includes two items from each of seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. The patient answers each item on a 5-point Likert scale resulting in a total score with higher scores being indicative of poorer oral health-related quality of life. The OHIP-14 has demonstrated good reliability, validity (Slade 1997) and has been translated into many languages and used clinically throughout the world (Slade, 1997).

Generalized Anxiety Disorder GAD-7. The GAD-7 (Spitzer, Kroenke, Williams, & Lowe, 2006) is a 7-item measure used to assess presence of symptoms of generalized anxiety over the previous two weeks. The GAD-7 is a widely used assessment instrument and has demonstrated good psychometric properties in clinical and research applications (Spitzer et al., 2006).

Patient Health Questionnaire-9 (PHQ-9). The PHQ-9 (Kroenke, Spitzer, & Williams, 2001) is a 9-item measure of the presence and severity of depressive symptoms over the previous two weeks. Test-retest reliability, internal consistency, and convergent validity have been established (Kroenke et al., 2001).

VAS measures. The following VAS (Visual Analog Scale) measures were completed by all study participants after the completion of dental treatment on the intervention days.

Each VAS will be 100mm lines anchored at each end with descriptors.

1. Please place a slash (/) on the line below to indicate your present level of comfort.
2. Please place a slash (/) on the line below to indicate your present level of anxiety.

Therapy Satisfaction Scale. Participants was asked to rate their satisfaction with the intervention Program using a 5-point scale ranging from “Strongly disagree” to “Strongly agree”. This measure has eight items assessing participant satisfaction and perceived impact of the intervention in dental anxiety.

Physiological Measures

All patients were assessed physiologically using Heart Rate Variability (HRV) recorded with the Bodyguard Heart Rate devices (Firstbeat Technologies, Ltd., Jyväskylä, Finland). The Bodyguard is a portable heart rate measurement device with an extended data storage capacity for up to 14 days. It overcomes the limited versatility and data storage of an ECG. This device is smaller than a traditional Holter monitor, easy to connect and uses two disposable surface electrodes. The Bodyguard has been used in clinical and research applications (Fohr et al, 2015). To analyze the heart rate recordings, Firstbeat Athlete Software will be used (version 2.1.0.8(3.1.3ov). This software scans the recorded ambulatory RR interval data through an artifact detection filter to perform an initial correction of falsely deleted, missed, and premature heart beats. The HRV analyses will be completed using the Nevrokard Advanced HRV analyses software

(version 10.1.0) for time and frequency domain analyses (Nevrokard Kiauta, k.d., Slovenia). For this study, time-domain SDNN (standard deviation of the NN intervals) and RMSSD (root mean square of the successive differences of the NN intervals) values will be calculated as well as frequency domain FFT non-parametric HRV values in normalized units (LF, HF, and LF/HF ratio).

Data Analysis Plan

Sample Size Estimation: Sample Size Estimation: This study is a pilot study with 34 evaluable subjects (17 in each group), planning to enroll up to 44 participants to account for attrition. The primary aim of this study is to test feasibility of both the dog exposure treatment and the physiological measurements. This number of subjects likely does not provide adequate power to address Aims 2 and 3, but will provide future studies with important data concerning the intervention's anticipated effect size on both self-reported and physiological measures.

Data Analysis:

Due to lack of sufficient subjects in the study so far, the data analyzed for this paper was based on fifteen subjects who have completed the study. However once sufficient number of subjects complete the study, the data will be presented using the guidelines of the CONSORT statement as follows since the patient selection was randomized:

1. A flow diagram of the participants' progress through the phases of clinical trial (e.g. enrollment, intervention, allocation, follow-up, and data analysis) will be presented.
2. All data will be analyzed primarily as intention-to-treat.
3. A table of baseline demographic and clinical characteristics will be presented using

means and standard deviations for continuous normally distributed data, medians with ranges (interquartile or minimum-maximum) for continuous or ordinal data that are not normally distributed and counts with proportions for categorical data.

Distribution of data will be examined using the Shapiro Wilk test and visual inspection with histograms.

4. Overall patient levels of Dental Anxiety and Dental Fear and Generalized Anxiety Disorder will be reported. Similarly, overall patient Oral Health and Patient Health will be reported.
5. Specific Aim 1. The feasibility of the intervention will be described, including counts of any adverse events or adverse interactions with the therapy dogs, or any difficulty experienced using the physiological measurement devices. Study attrition in each of the groups will be described.
6. Specific Aim 2. The patient-reported satisfaction with the treatment will be described using counts of ratings on the 5-point Therapy Satisfaction Scale to evaluate the feasibility of a larger study with therapy dogs.
7. Specific Aim 3. The efficacy of the therapy dog intervention will be evaluated by reporting and comparing patient-reported post-treatment VAS scores in the treatment and control group. Primarily, the means and standard deviations (or medians and ranges) of these data will be presented separately for each group, to allow future research to estimate an appropriate sample size to detect any possible differences. Secondly, scores on the post-treatment VAS for both comfort and anxiety will be analyzed across participants using a linear mixed-effects model or

generalized estimating equation to control for multiple measurements by each participant.

RESULTS

Patient recruitment began in April 2017 for this ongoing study. Currently, 22 participants have been enrolled in the study. Fifteen participants (n=15) have completed the study, with 10 enrolled in the DOG group and 5 in SC group. Two patients are currently enrolled in the study, but have not yet completed all study requirements at the time of this writing. Lastly, five participants dropped out of the study due to permanent change of station transfers. Of the participants that completed the study, the age ranged from 19-51 years, with a median age of 35.1 years (SD=11.4). Eleven (73%) of the participants were female and four (27%) were male. Due to the limited number of participants in the study, heart rate variability data has not been analyzed yet. This data will be analyzed and reviewed at a later date, as more data are added. However, there are several self-reported psychological measure that appear to be relevant. In order to maximize the use of available data, current data analysis used information obtained from the first two intervention sessions on fifteen participants that have completed the study. These intervention sessions are labeled T1 and T2 respectively.

Analysis of the Index of Dental Anxiety and Fear-4C Scores, at T1 and T2 is provided in Figure 2. Participants in the DOG group (n = 10) had a mean score of 3.71 (SD=1.1) at T1 and 3.32 (SD=1.4) at T2. For the control group (n=5), IDAF dental anxiety scores were mean = 3.15 (SD=0.5) at T1 and 3.2 (SD=0.8) for T2. These

differences were not statistically significant (repeated measures ANOVA: $F=1.817$, $p=0.201$). Additionally, the changes in dental anxiety mean scores were not significantly different between groups at each assessment (univariate ANOVA at T1: $F=1.061$, $p=0.322$; univariate ANOVA at T2: $F=0.34$, $p=0.856$).

IDAF-4C Dental Anxiety Triggers are shown for T1 (Figure 3) with highest scores being reported for the DOG group (scores ≥ 2.5): Pain 3.7 (SD = 1.4), Lack of Control 3.3 (SD = 1.6), Unkind Dentist 2.7 (SD = 1.8), Needles 2.6 (SD = 1.4), Gagging/Choking 2.5 (SD = 1.4), and Embarrassed 2.5 (SD = 1.7). For the Control group, the highest scores reported at T1 (scores ≥ 2.5) were Pain 4.0 (SD = 1.0), Needles 3.0 (S.D. = 1.6), Lack of Control 2.8 (SD = 1.1), Unkind Dentist 2.8 (SD = 0.8), Gagging/Choking 2.6 (SD = 1.8), and Not Knowing What Dentist Is Doing 2.6 (SD=0.5).

The Dental Anxiety Triggers are shown for T2 (Figure 4) with highest scores being reported for the DOG group (scores ≥ 2.5): Pain 3.5 (SD = 1.7), Unkind Dentist 2.9 (SD = 2.0), Lack of Control 2.6 (SD = 1.6), Gagging/Choking 2.4 (SD = 1.5), and Needles 2.4 (SD = 1.6). The dental anxiety triggers for the control group that were highest at T2 (scores ≥ 2.5): Pain 4.2 (SD = 1.1), Needles 2.6 (S.D. = 1.5), and Lack of Control 2.6 (SD = 1.1).

For Anxiety Triggers in the DOG group, “Lack of Control” ($F=10.80$, $p=0.010$) and “Feeling Sick or Queasy” ($F=6.00$, $p=.037$) significantly decreased from T1 to T2 ; (Figure 5). There were no other statistically significant changes in the rated severity of dental anxiety triggers between T1 and T2 in either group.

The Generalized Anxiety Disorder scale was used to assess general symptoms of anxiety. This measure has a range of 0-21 with scores in the 5-9 range indicating mild

anxiety, 10-14 indicating moderate anxiety, and 15 and greater indicating severe generalized anxiety. There was no significant difference between groups or between the two assessments on GAD scores: repeated measures ANOVA: $F=0.76$, $p=.398$. There was also no significant difference between scores by group at each assessment. Dog Group mean at T1: 8.3 (SD=7.2), Control Group mean at T1: 6.0 (3.2), $p=0.512$; Dog Group mean at T2: 7.7 (SD=7.8), Control Group mean at T2: 5.4 (SD=3.1), $p=0.544$. See Figure 7 for GAD scores. The mean scores from both groups at both assessments fell within the mild range for generalized anxiety.

A similar analysis was completed on the scores from the Patient Health Questionnaire, which is an assessment of depressive symptoms. This measure is scored on a range of 0-27. Scores in the 5-9 range suggest mild depressive symptoms, 10-14 are moderate, 15-19 are moderate-severe, and over 19 suggest the respondent is experiencing severe symptoms of depression. There was no significant difference between groups or between the two assessments on PHQ scores: repeated measures ANOVA: $F=1.94$, $p=.188$. There was also no significant difference between scores by group at each assessment. Dog Group mean at T1: 7.6 (SD=7.7), Control Group mean at T1: 4.4 (4.4), $p=0.412$; Dog Group mean at T2: 6.8 (SD=7.4), Control Group mean at T2: 4.6 (SD=4.9), $p=0.562$. See Figure 8 for PHQ scores. The mean scores from both groups at both assessments fell at or below the mild range for symptoms of depression.

Two Visual Analog Scales (VAS) were completed by all study participants at the completion of the dental appointment. The first VAS asked the participant to rate current level of anxiety. There was no statistically significant difference on VAS anxiety by group between the two time points using repeated measures ANOVA ($F=.035$, $p=0.855$).

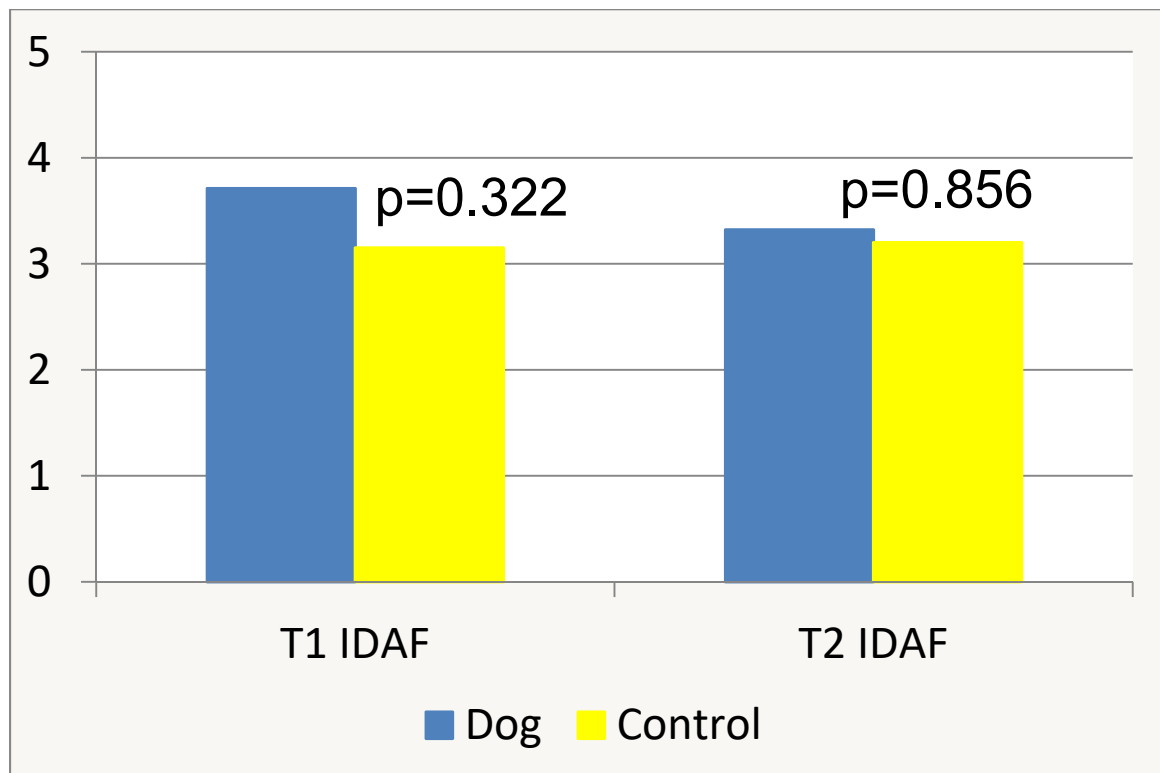
When the groups were compared at each time point, there was not a statistically significant difference at T1 (Dog Group mean at T1 = 38.3 (SD=22.3), Control Group mean at T1= 57.8 (SD=9.4); $F=3.42$, $p=0.087$), there was a significant difference at T2 with the Dog Group reporting lower VAS anxiety (Dog Group mean at T2 = 32.4 (SD=20.9), Control Group mean at T1= 54.4 (SD=6.2); $F=5.10$, $p=0.042$). See Figure 9.

When compared on scores from the VAS comfort measure, no statistically significant differences were found by group over time using repeated measures ANOVA ($F=.022$, $p=0.883$). There were also no statistically significant differences between group at either time point using univariate ANOVA (Dog Group mean at T1 = 71.9 (SD=19.0), Control Group mean at T1= 55.4 (SD=16.6); $F=2.72$, $p=0.123$; Dog Group at T2 = 68.9 (SD=19.5), Control Group mean at T2= 50.8 (SD=19.4); $F=2.87$, $p=0.114$). See Figure 10.

Participants in the DOG group ($n = 10$) also completed the Therapy Satisfaction Survey (TSS) at the end of each time point. This measure has a range of 0-35 with higher scores indicating higher level of satisfaction. Participants reported TSS mean score of 33.8 at T1 (SD=4.1) and 34.7 at T2 (SD=2.7) suggesting that all participants in the Dog Study group were highly satisfied with the therapy dog intervention.

FIGURE 2

IDAF-4C Mean Dental Anxiety Scores by Group



Note. IDAF-4C, Index of Dental Anxiety and Fear.

FIGURE 3

IDAF-4C Triggers at T1

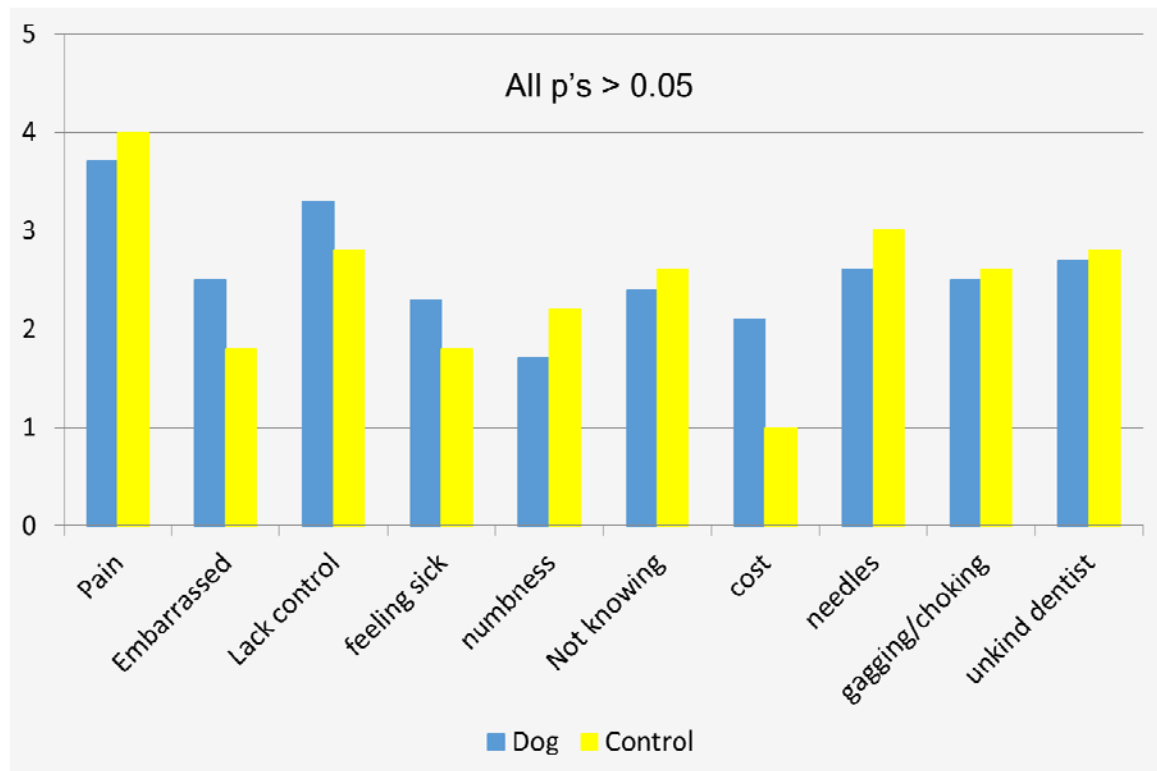


FIGURE 4

IDAF-4C Triggers at T2

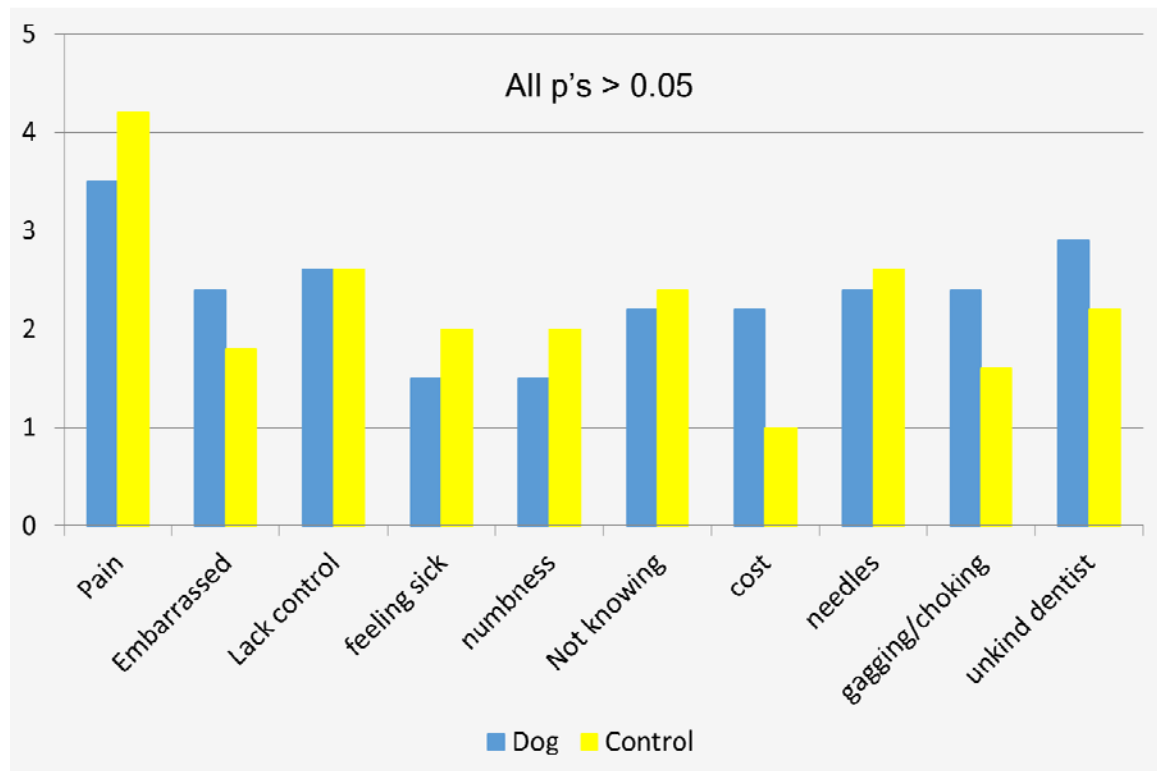


FIGURE 5

IDAF-4C TRIGGERS AT BOTH ASSESSMENTS, DOG GROUP ONLY

Dental Anxiety Trigger	Time 1	Time 2	P
Pain	3.7 (1.4)	3.5 (1.7)	0.443
Embarrassed	2.5 (1.7)	2.4 (1.9)	0.726
Lack of control	3.3 (1.6)	2.6 (1.6)	0.010
Feeling sick or queasy	2.3 (1.4)	1.5 (1.1)	0.037
Numbness	1.7 (1.3)	1.5 (1.3)	0.168
Not knowing what dentist is doing	2.4 (1.7)	2.2 (1.5)	0.509
Cost	2.1 (1.8)	2.2 (1.8)	0.343
Needles/Injections	2.6 (1.4)	2.4 (1.6)	0.443
Gagging/Choking	2.5 (1.4)	2.4 (1.5)	0.591
Unkind or unsympathetic dentist	2.7 (1.8)	2.9 (2.0)	0.168

Note. Index of Dental Anxiety, repeated measures ANOVA completed on each trigger.

FIGURE 6

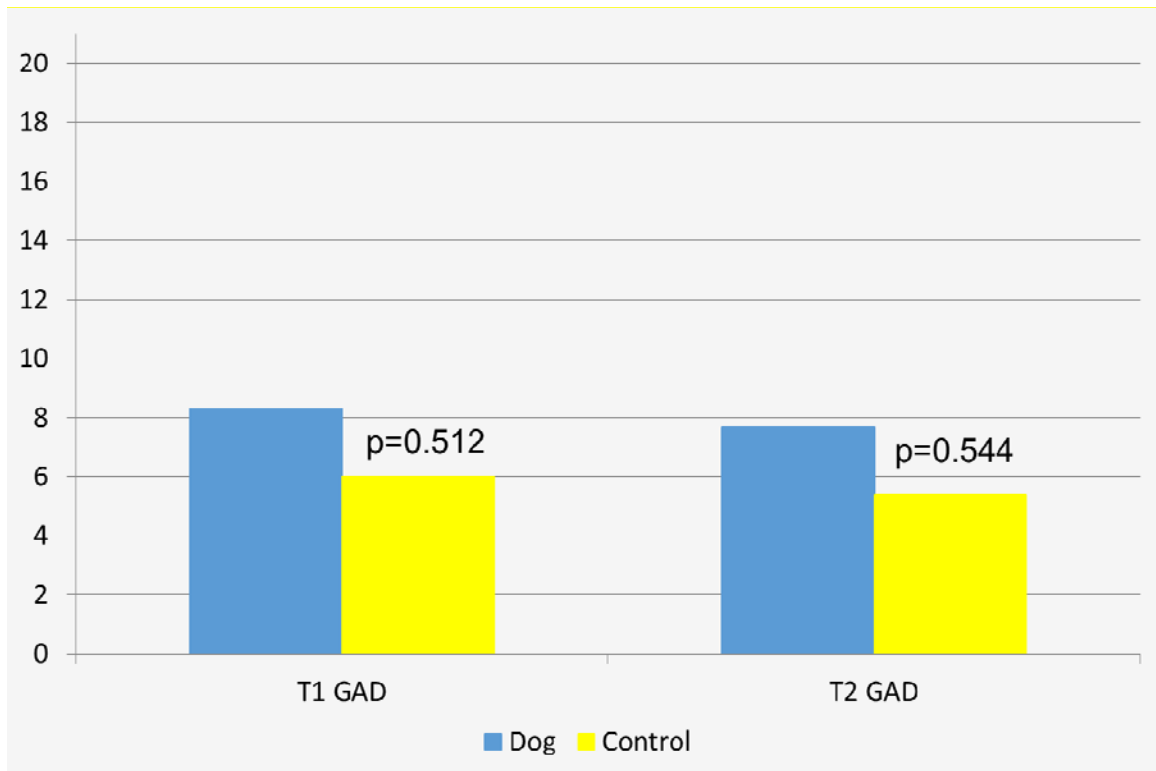
IDAF-4C TRIGGERS AT BOTH ASSESSMENTS, CONTROL GROUP ONLY

Dental Anxiety Trigger	Time 1	Time 2	P
Pain	4.0 (1.0)	4.2 (1.1)	0.704
Embarrassed	1.8 (1.1)	1.8 (0.8)	1.000
Lack of control	2.8 (1.1)	2.6 (1.1)	0.621
Feeling sick or queasy	1.8 (0.8)	2.0 (0.7)	0.621
Numbness	2.6 (0.5)	2.4 (0.9)	0.374
Not knowing what dentist is doing	2.4 (1.7)	2.2 (1.5)	0.509
Cost	1.0 (0.0)	1.0 (0.0)	1.000
Needles/Injections	3.0 (1.6)	2.6 (1.5)	0.178
Gagging/Choking	2.6 (1.8)	1.6 (0.9)	0.142
Unkind or unsympathetic dentist	2.8 (0.8)	2.2 (0.8)	0.070

Note. Index of Dental Anxiety, repeated measures ANOVA completed on each trigger.

FIGURE 7

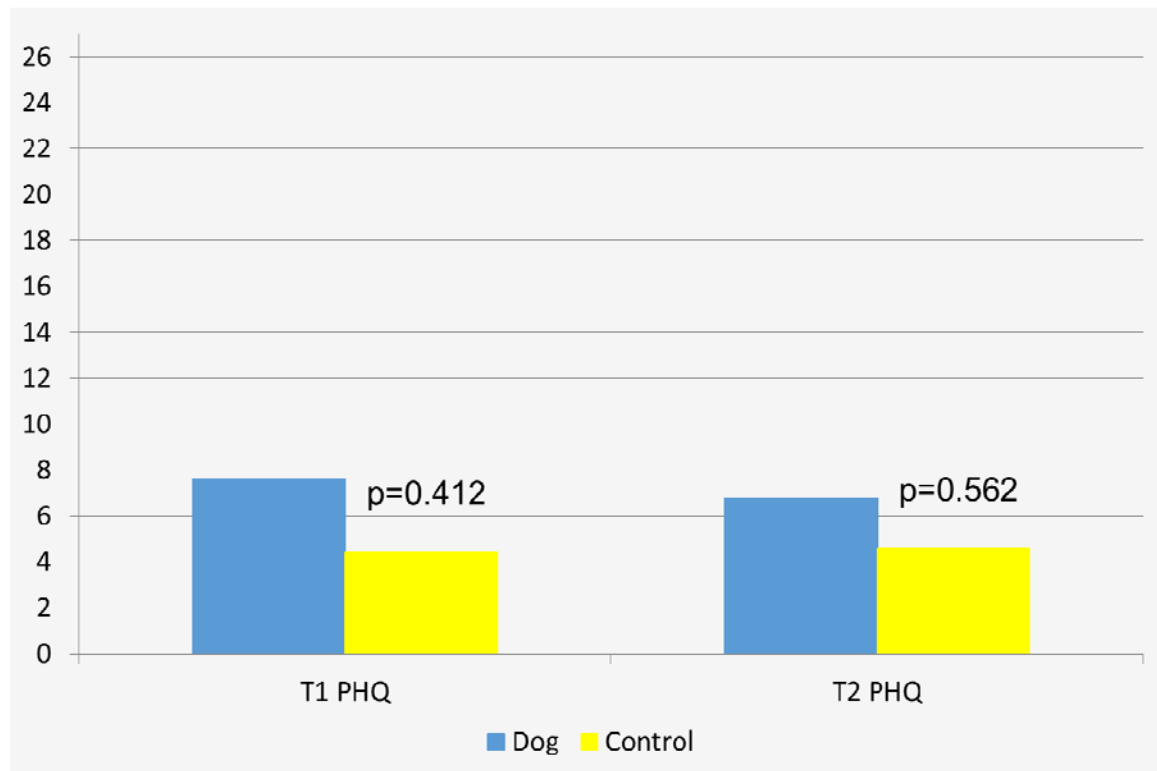
GAD-7 MEAN SCORES AT BOTH ASSESSMENTS



Note. GAD-7; Generalized Anxiety Disorder, repeated measures ANOVA.

FIGURE 8

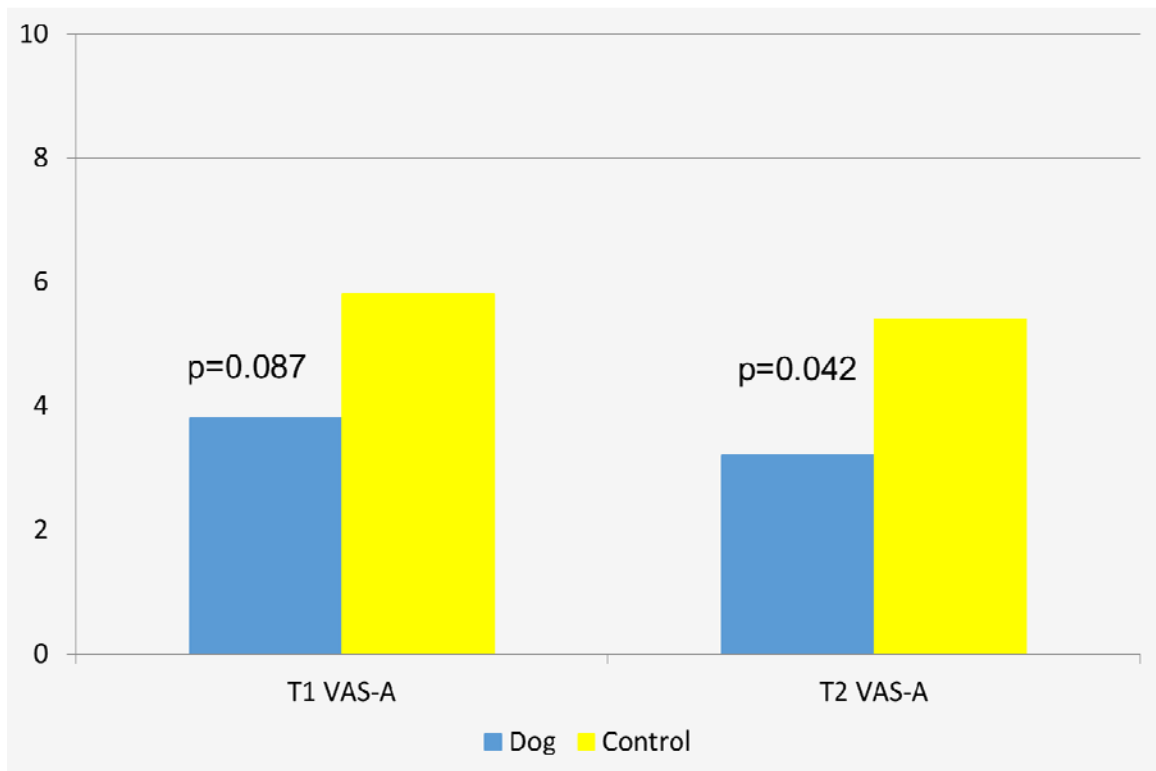
PHQ-9 MEAN SCORES AT BOTH ASSESSMENTS



Note. PHQ-9; Patient Health Questionnaire, repeated measures ANOVA.

FIGURE 9

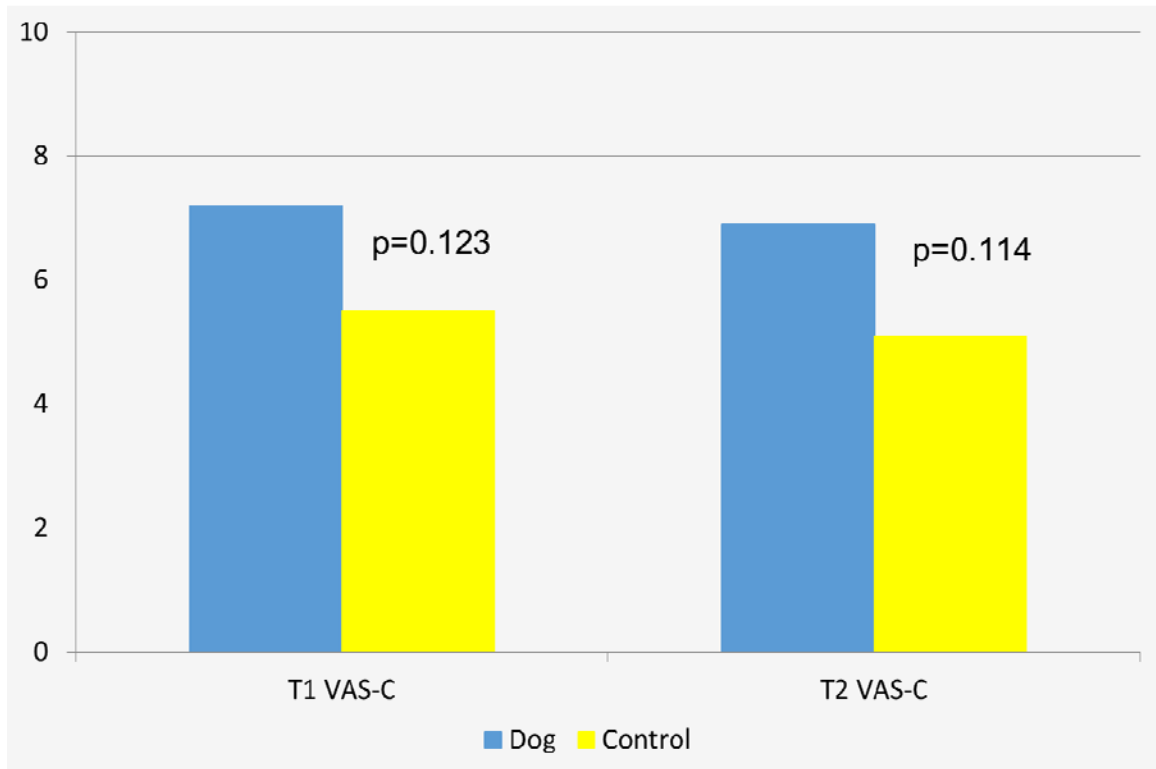
VAS ANXIETY



Note. VAS-A; Visual Analog Scale - Anxiety.

FIGURE 10

VAS COMFORT LEVEL



Note. VAS-C; Visual Analog Scale – Comfort level.

DISCUSSION

IDAF-4C mean scores for dental anxiety indicate that the study participants were indeed experiencing significant dental anxiety, as all participants reported IDAF-4C scores above the cutoff score of 2.5. However, neither group demonstrated a significant decrease in dental anxiety between the two time points. While this was not surprising for the Control Group, we did expect participants in the Dog Group to report lower dental anxiety at the second visit. The reasons for this lack of change in reported dental anxiety in the Dog Group could be attributed to the fact that our intervention did not directly treat dental anxiety. The use of the therapy dogs may help the patient relax and be more at ease at the start of treatment and perhaps more likely to show up and follow-through with treatment appointments, but therapy dogs are not an intervention that is designed to address a specific medical or psychological issue. For example, McCracken and LaJoie tested the effect of a therapy dog on pediatric and adolescent patients' anxiety while receiving treatment at a gynecology office. The results were mixed with 63% of the patients reporting a decrease in anxiety after interacting with the therapy dog, 26% reporting no anxiety change, and 10% stating their anxiety increased following therapy dog interaction. That said, 94% of those that received a therapy dog reported a positive experience (McCracken & LaJoie, 2016).

IDAF-4C Dental Anxiety Trigger analysis between the two time points yielded interesting results. Participants in both the DOG and control groups showed decreases in anxiety provoking triggers, with the following being the most common triggers that

decreased in reported severity for both groups: Pain, Needles, Lack of Control, Unkind Dentist, and Gagging/Choking. However, most of these decreases were not statistically significant. Participants in the Dog Group did have two triggers which decreased significantly between the two time points: “Lack of Control” and “Feeling Sick or Queasy.” It is possible that the time spent with the dogs allowed the participants to relax and feel more in control of the situation while also serving as a healthy distraction from the typical rumination that patients with dental anxiety experience when waiting for treatment to start. The dog interactions may have resulted in decreases somatic symptoms (feeling sick or queasy) and a general increase in well-being right before the start of treatment. This change may have resulted in an increase in feelings of control over the situation. This change was not evident in the Control Group participants. Similarly, Orlandi and colleagues reported that chemotherapy patients that utilized therapy dogs showed unchanged somatic symptoms associated with their chemotherapy, compared to a significant 31% increase in aggravation within the control group (Orlandi et al., 2012).

All study participants completed commonly used measures to assess symptoms of anxiety (Generalized Anxiety Disorder scale – GAD) and depression (Patient Health Questionnaire – PHQ). There was no significant difference between the two groups on these measures at either time point and no significant change between time points for either group as well. The average score for both groups at both time points was in the mild range. This indicates that study participants were generally experiencing mild symptoms of both anxiety and depression and the study intervention did not impact these symptoms.

The most promising support for the use of therapy dogs in the dental setting from this study comes from VAS-Anxiety mean scores. The participants in the Dog Group reported a significant decrease in VAS-Anxiety between the two time points when compared to the Control Group participants. This difference in current severity of feelings of anxiety between the two groups is especially interesting since the VAS was completed at the end of the dental appointment. In some cases, this was more than an hour after the therapy dog intervention and suggests that the benefit of the therapy dog interaction had an impact on anxiety throughout the entire dental visit. The other VAS assessed level of comfort at the end of the dental appointment. However, there was no significant change over time or between groups on this measure.

All participants in the Dog Group completed a measure to assess therapy satisfaction, which was focused specifically on satisfaction with the therapy dog interaction. All Dog Group participants indicated a high degree of satisfaction with the intervention, with no negative reports or feedback.

Study Limitations

The primary limitation of this study is the small sample size. Despite active recruitment within all dental departments at the Naval Postgraduate Dental School and Walter Reed dental clinics, it was challenging to recruit patients for the study. Many of the candidates referred to the study did not meet the minimum three dental treatment visits, due to limited dental treatment needs. This may be a function of the patient population served in the Washington DC area, as well as the high number of

Medical/Dental professionals that are treated at this facility as patients. Additionally, there were multiple therapy dogs and dog handlers utilized at various times. As a result, the therapy dog interactions are not as ideally controlled since participants may interact differently with each dog. That said, substantial effort was made to use the same dog with the same participant whenever possible. Finally, the participants generally had the same dental practitioner throughout study participation. Therefore, it is possible that the participants became more relaxed and comfortable with their dentist. Finally, we have not yet analyzed the objective heart rate variability data, due to limited population. That said, this objective data is the most interesting portion of this research and its absence represents a significant limitation.

CONCLUSION

This study demonstrates good efficacy and acceptability for the use of therapy dogs with patients struggling with treatment-interfering dental anxiety. Therapy dogs are becoming more frequently used in medical settings, but have not been utilized in dental settings. The results from this ongoing study suggest that the use of therapy dogs is feasible in the dental setting from both the patient and treatment team perspective. Further, therapy dog, as an adjunct modality may reduce the need for standard pain and distress management techniques. Standard techniques are costly and have associated risks.

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