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

by

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CERTIFICATE OF APPROVAL

MASTER'S THESIS

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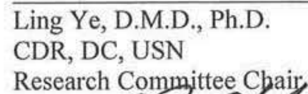

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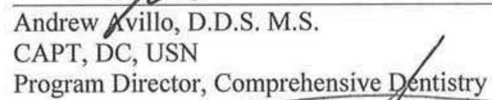

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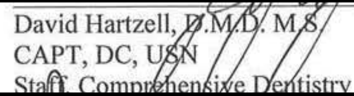

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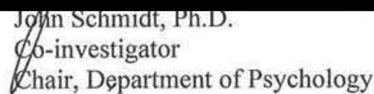

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ABSTRACT

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

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INTRODUCTION: There has been an increase in the use of therapy dogs in recent years to help people cope with anxiety provoking situations. Visiting a dentist is one of the most stressful situations for many. Some dentists simply avoid the issue, while others resort to pharmacological interventions, but there is a risk to using medications. Patients with dental anxiety often are in a vicious cycles of avoidance of dental care and poor oral hygiene resulting in serious dental problems. Recent studies have shown that therapy dogs can have psychological benefits in medical settings and in pediatric dental care. However, there has not been any data on how therapy dogs impact 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 results for this ongoing IRB approved study (currently N=7) show that patients are open to using therapy dogs to help manage dental anxiety. However, no significant change was noted in dental anxiety or other study measures (p's>0.05). DOG group participants did report significantly higher comfort level after dental procedure compared to control group participants on a Visual Analog Scale ($p<0.05$).

CONCLUSIONS: Therapy dog intervention for adults with dental anxiety may be effective and less costly or risky compared to standard pharmacological interventions such as anxiolytics. Patients with treatment interfering dental anxiety may be more willing to maintain regular dental visits if therapy dogs are integrated into clinical visits.

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LIST OF ABBREVIATIONS

Abbreviations Page

1. DOG – Therapy Dog intervention group ii
2. SC- Standard Care ii
3. IRB- Internal Review Board iii
4. ECG- ElectroCardioGram 6
5. IDAF– Index of Dental Anxiety and Fear 6
6. VAS – Visual Analog Scale 6
7. NPDS- Naval Postgraduate Dental School 7
8. AEGD- Advanced Education in General Dentistry 7
9. DHQ- Dental Health Questionnaire 7
10. TSS – Therapy Satisfaction Scale 9
11. OHIP – Oral Health Impact Profile 16
12. GAD- Generalized Anxiety Disorder 16
13. PHQ – Patient Health Questionnaire 16
14. HRV – Heart Rate Variability 17
15. SDNN - Standard Deviation of the NN intervals 18
16. RMSSD - Root Mean Square of the Successive Differences 18

REVIEW OF THE LITERATURE

There are many victims under extreme distress in today's society due to various unfortunate events. For such victims, the use of therapy dogs has been rising in popularity which has allowed them to cope with such extreme distress and anxiety (Neale and Fretland, 2018). The use of therapy dogs even made headlines recently as they greeted Parkland high school students when they returned to school for the first time since the mass shooting in their school (Chorney, 2018). In addition to distressed victims, therapy dogs have been utilized in airports, court rooms, hospitals and numerous other avenues to lend comfort to those that were under stress and feeling anxious (Neale and Fretland, 2018). Even at Mayo clinic, the call to make "animal-assisted therapy" more available has been growing due to "consistent and overwhelming" data which supports the benefit of the therapy in certain circumstances (Creagan, Bauer, Thomly and Borg, 2015). Of all the situations that cause anxiety or fear in people, one of the most common situations is getting dental treatments (Carter, Carter, & Boschen, 2014). What is it about dogs that allow such comfort in those who interact with them? Would interaction with dogs be helpful in relieving the stresses of dental patients? This review of literature will examine the basis to support the hypothesis of the efficacy of therapy dogs with adult patients with dental anxiety.

What is anxiety? Stefenac and Nesbit (2017) defines anxiety as "both a physical and emotional response to an anticipated experience that the individual perceives as threatening in some way". When this anxiety becomes focused on the anticipation of a dental visit, creating an emotional state which lead to physical, cognitive, emotional and

behavioral responses, this can be categorized as dental anxiety (Appukuttan, 2016). When such anxiety affects an estimated 14 to 34 million people in the United States alone, who often avoid seeking dental care, this becomes a significant societal issue (Melamed, 2018). In a variety of surveys regarding phobias and fears, going to the dentist is always ranked at or near the top along with public speaking, snakes, heights and spiders (Melamed, 2018). Unfortunately, dentists often like to disregard or downplay the fact that what they do is a great source of anxiety and fear, even though there are unmistakable evidences to show that anxiety can lower the pain threshold and play a significant role in the remembrance of exact level of dental pain during a dental procedure (Stefenac and Nesbit 2017). Managing patients with dental anxiety creates great challenges for all dentists and makes it much more likely that such patients will be trapped in the vicious cycle of having serious dental problems due to avoidance of dental care.

Dentists must take steps to properly manage patients with dental anxiety to avoid the trap that dental anxiety can create for the patients. The management of dental anxiety generally falls into the two broad categories of psychotherapeutic methods or pharmacologic interventions (Appukuttan, 2016). Psychotherapeutic methods include behavior or cognitive approaches, while pharmacologic interventions provide either conscious sedation or general anesthesia (Appukuttan, 2016). There are multiple ways to utilize psychotherapeutic or cognitive methods to manage anxious dental patients, which focus on reducing the level of anxiety by distraction, sensory focusing, positive reinforcement, cognitive restructuring, or systemic desensitization (Burghardt et al., 2018). Furthermore, hypnosis, acupuncture and music interventions have been explored

for reducing dental or medical anxiety and have shown to to reduce stress and adjust patient expectations for more positive outcomes (Burghardt et al., 2018). Although these methods are known to be effective, these methods are often not practical for many dentists due to time, effort, and risks that they entail, and they are also not practical for most patients in terms of cost or dealing with its side effects and risks.

Considering the economics of dentistry, the use of sedation or general anesthesia makes the most sense. However, a recent telephone survey of over 1100 people in Canada paints a picture in which even the availability of effective pharmacological intervention is not the solution. This survey noted that 5.5% of the participants admitted to having "high fear" of getting dental treatments, but of the 5.5%, only 31% were "definitely interested" in getting dental treatment if sedation or general anesthesia was available, which means that 69% were either not interested or would only be interested if the cost was reasonable (Melamed, 2018). In the United States, a similar survey determined that only 18% of patients with dental anxiety would be interested in more dental visit if sedation was available to them (Melamed, 2018).

Furthermore, while it is commonly assumed that all patients with dental anxiety have had traumatic dental issues in the past, evidence suggests that it is not always the case (Stefanac and Nesbit, 2017). How these patients perceive their dental experience, whether it is the perception of losing control or the sudden urge for personal control, can often lead to future dental anxiety (Stefanac and Nesbit, 2017). Furthermore, there is increased evidence of a relationship between dental anxiety and history of sexual/physical abuse (Stefanac and Nesbit, 2017). Understanding the cause and effects

related to dental anxiety can lead to a profound realization that it is a concern that must be addressed and not put to the side by practitioners in all medical and dental fields.

What does this all mean? This points to a grim reality for patients who have dental anxiety or fear, where there is no clear-cut solution to help them get the dental care they desperately need and to take them out of the vicious cycle of dental anxiety. This is where the potential of animal-assisted therapy, especially with dogs, come into place. There have been growing evidence that supports the efficacy of using animal-assisted therapies as "complementary or adjunctive therapy for various clinical conditions" (Mani and Weese, 2016). It has been known for decades that human-dog interactions lead to lower blood pressure and reduced heart rate, but studying the efficacy of therapy dogs in clinical settings has been slow to gain traction (Vormbrock J. and Grossberg J., 1988). In a recent study, therapy dog visitation was associated with a reduction in pain severity in fibromyalgia patients, while other therapy dogs have been associated with decrease in postoperative or other pain in pediatric patients (Mani and Weese, 2016).

The benefits of therapy dogs do not end there. Other studies have shown that animal-assisted therapy triggers physiologically measureable reduction in stress, pain, fatigue, and anxiety while increasing positive mood and other "clinical variables" (Mani and Weese, 2016). A study by McCracken et al. tested the effect of therapy dogs on teenagers (n=60) during their first visit to a gynecology office. Half of the patients (n=30) interacted with therapy dogs and 93% (n=28) had admitted to having a positive interaction with the dogs. Of the patients randomized to the dog intervention, 63% (n=19) reported having noticeably reduced anxiety after the interaction (McCracken et al, 2016). Furthermore, the American Heart Association made a definitive, scientific

statement regarding the healing power of pets in 2013 stating that interaction with pets lead to improvement in hypertension, hyperlipidemia, physical activity and obesity (Creagan et al., 2015).

All the mounting data of confirming the benefits of interaction with therapy dogs naturally leads to the question: What is the physiologic effect of therapy dogs? The answer apparently lies with hormonal changes that the interaction with the dogs produce. There is growing evidence that positive interactions with dogs trigger release of hormones associated with social bonding, pain reduction and pleasure such as oxytocin, prolactin, dopamine and beta-endorphins (Mani and Weese, 2016). Evidently, physical contact with animals such as stroking a dog or grooming a cat is what triggers the enhancement of "happy hormones" mentioned above as well as the reduction of stress hormone cortisol (Creagan et al., 2015). Of the "happy hormones", studies have focused on oxytocin, which is typically known as the hormone that facilitates bonding at birth and promotes feelings of contentment and trust. The release of oxytocin has been measured in participants by merely being in the presence of a dog, especially during mutual gaze (Finn-Stevenson, 2016).

The effects of oxytocin became known in the 1990's when it was discovered that breastfeeding mothers are calmer under psychosocial stress than bottle-feeding mothers mainly due to the difference in oxytocin levels (DeAngelis, 2008). Oxytocin has been clearly linked to maternal behavior, lactation, selective social behavior and pleasures and it has been shown that the level of oxytocin increases in the body under stressful conditions (DeAngeleis, 2008). It was discovered in 2011 that in addition to reproductive and social functions, oxytocin has been identified as a cardiovascular hormone which

activates "an anti-stress response that reduces cardiovascular and neuroendocrine stress reactivity" (Grewen and Light, 2011).

Based on the evidence, oxytocin represents a possible link between the reduction of dental anxiety in adult patients and the effectiveness of therapy dogs. The relationship between cardiovascular effects and dental anxiety or fear has been well documented and established (Johnsen et al, 2003). This study has two hypotheses:

1) The patients randomized to the therapy dog intervention group will find the interaction acceptable and the interactions will be feasible.

2) The patients in the therapy dog group will report lower levels of perceived anxiety and increased comfort after the intervention and dental procedures when compared to the control group.

Materials and Methods

Participants: Study participants will be 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 will require 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 will require multiple treatment sessions and will be treated by one of the residents in the Comprehensive Dentistry or AEGD training programs.

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

Inclusion criteria: age ≥ 18yrs, with dental anxiety, generalized or situational anxiety, and requiring 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 (N=44). 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. 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.

At Event 2 when the participant arrives for dental evaluation and treatment planning session, s/he completed self-report measures in the waiting area. The participant then was brought to the operatory and the Firstbeat device (ECG) was be attached. The Firstbeat device recorded ECG data throughout the procedure. At the end of the procedure, the device was removed. Following the treatment planning session, all participants were be randomized to a study condition (DOG or SC).

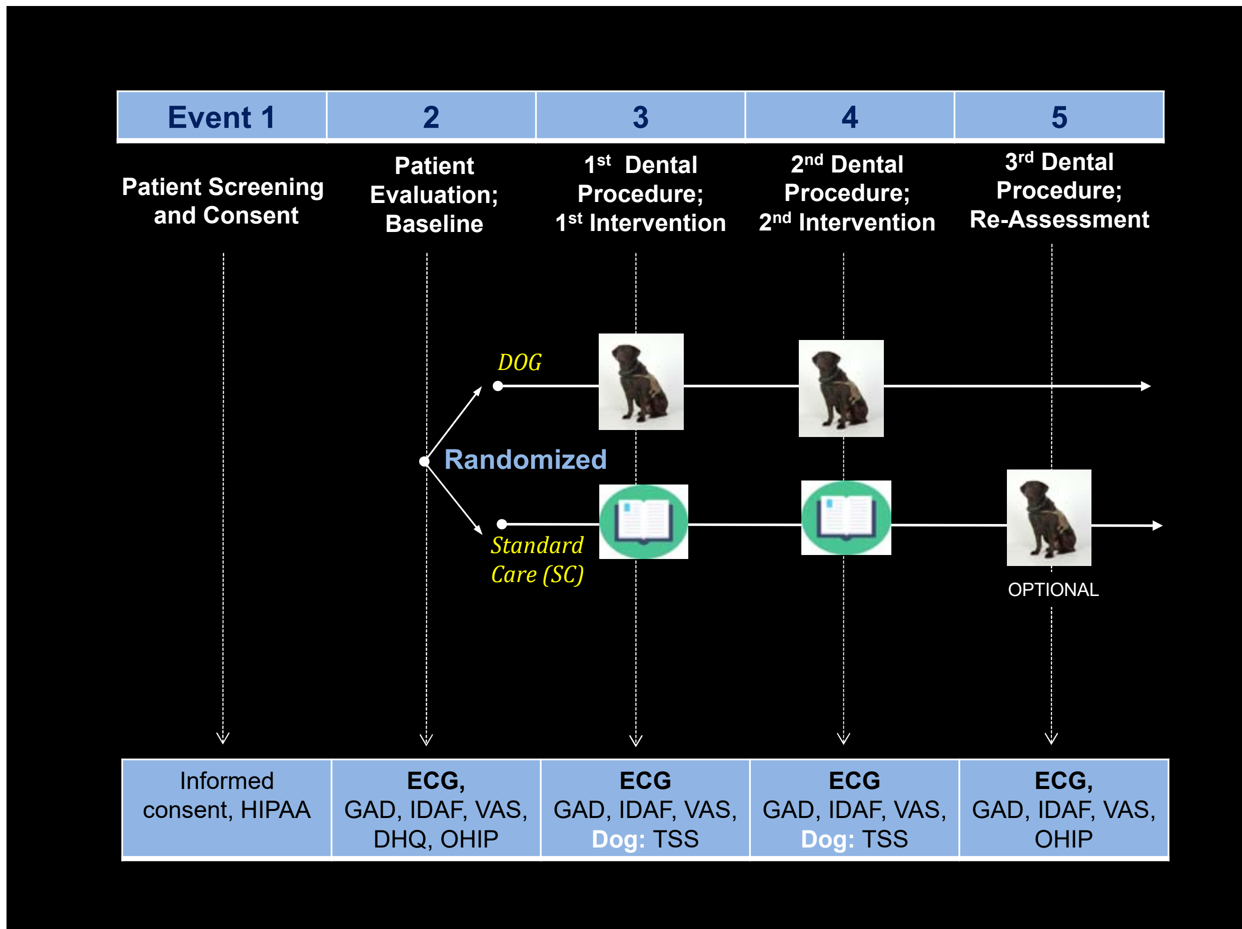
The intervention sessions for Events 3 and 4 took place at the first two dental treatment sessions. All study participants completed self-report measures in the clinic waiting area prior to treatment. Once the participant was brought back to the operatory, the Firstbeat ECG device was attached. Participants in the DOG group spent 10 minutes with a treatment dog accompanied by the study Principal Investigator (PI) 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 Events 3&4, participants in the DOG group also completed the Therapy Satisfaction Scale (TSS) after completion of the VAS. Any miscellaneous provider notes or notes from the dog handlers was 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 (Event 5) 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 was documented.

Participants in the SC group were given the opportunity to interact with the therapy dogs at Event 5. The final study session (Event 5) 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 was 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 was 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 the study PI 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 five of therapy dogs, therefore up to 5 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 completes 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 six 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. Secondarily, 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.

8. Specific Aim 4. The efficacy of the therapy dog intervention will be evaluated by comparing physiological measures in the treatment and control group. From the physiological data, time-domain and frequency-domain data will be extracted from the collected physiological data by means of specialized software (see Method for details). From these data, we will primarily present the means and standard deviations (or medians and ranges) of these data will be separately for each group, to allow future research to estimate an appropriate sample size to detect any possible differences. Secondarily, these physiological measures will be analyzed across participants using a linear mixed-effects model or generalized estimating equation to control for multiple measurements by each participant.
9. Exploratory Aim. Possible covariates that mediate dental anxiety will be identified. Due to the pilot nature of this study, this analysis will test single psychological, demographic, or oral-health covariates for possible influence on both patient-reported and physiological dental anxiety.

RESULTS

Even though the recruitment of patients started in April 2017, there have been difficulties recruiting patients for this study. So far nine patients have been enrolled in the study and of the 9 subjects, the data was analyzed based on six patients who have either completed the study or have completed multiple events to date. The interim data analysis of self-reported psychological measures has been completed based on the six subjects. However there was not enough data to analyze the physiologic assessment from the Bodyguard heart rate monitor.

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 event 2 and event 3 on six subjects which were labeled T1 and T2 respectively. On IDAF dental anxiety mean scores (figure 2), subjects (n = 6) scored 3.2 at T1 (S.D. = 1.3) and 3.1 at T2 (S.D. = 1.4), and on IDAF dental phobia mean scores (figure 3), subjects (n = 6) scored 3.0 at T1 (S.D. = 1.8) and 2.8 at T2 (S.D. = 1.7). On GAD mean score with range of 0 to 21 (figure 4), subjects (n = 6) reported mean score of 7.7 at T1 (S.D. = 7.8) and 6.5 at T2 (S.D. = 7.0). Those in the DOG group (n = 4) reported Therapy Satisfaction mean score of 36.7 at T1 (S.D. = 2.5) and 37.0 at T2 (S.D. = 4.3). The range of Therapy Satisfaction mean score is 0 to 40 (figure 5).

VAS Comfort mean score (figure 6) for subjects in DOG group was 84 at T1 and 88 at T2 whereas the mean score for subjects in SC group was 73 at T1 and 54 at T2.

VAS Anxiety mean score (figure 7) for subjects in DOG group was 20 at T1 and 33 at T2 while the mean score for SC group was 50 at T1 and 61 at T2.

Figure 2. Index of Dental Anxiety and Fear: anxiety mean score (IDAF-4C)

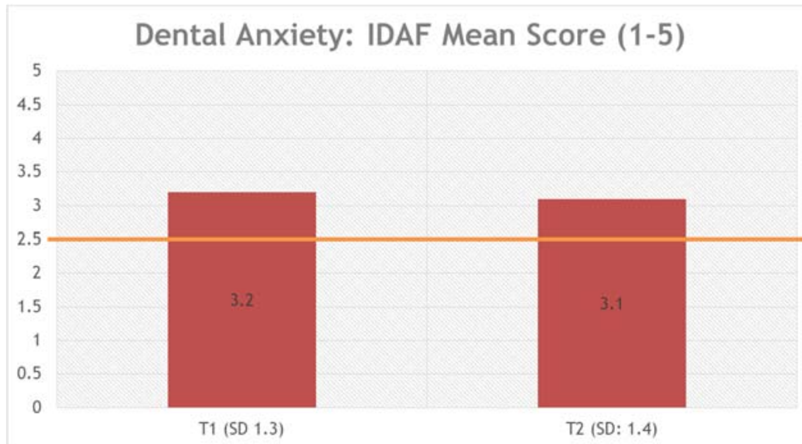


Figure 3. Index of Dental Anxiety and Fear: phobia mean score (IDAD-4C)

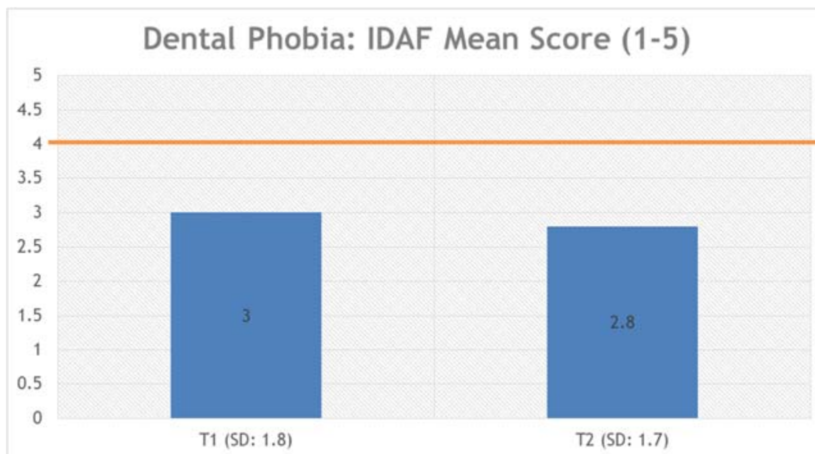


Figure 4. Generalized Anxiety and Depression (GAD-7)

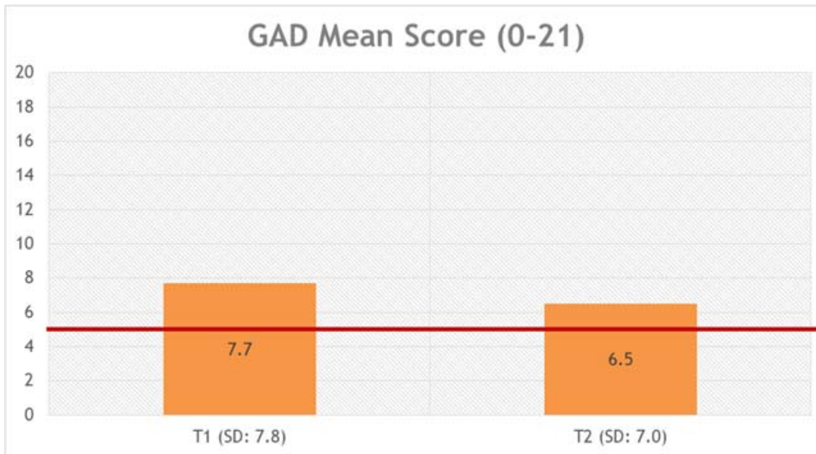


Figure 5. Therapy Satisfaction mean score

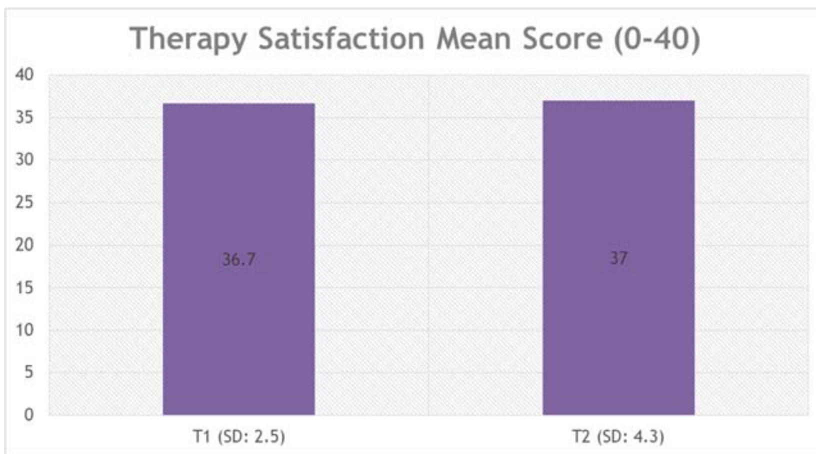


Figure 6. Visual Analog Scale comfort mean score

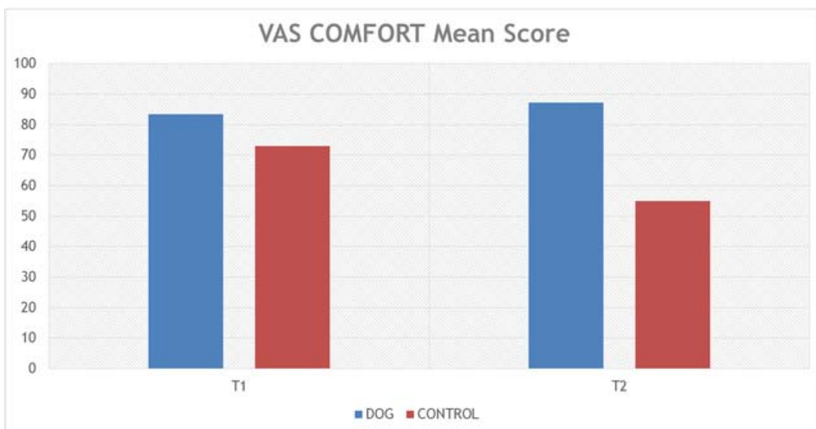
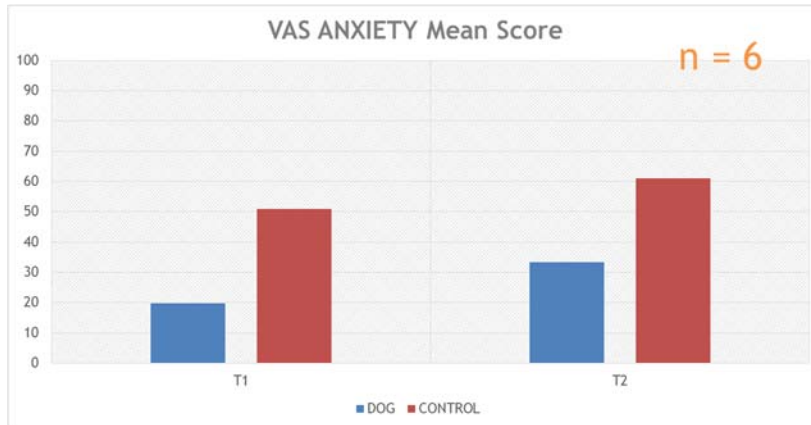


Figure 7. Visual Analog Scale anxiety mean score



DISCUSSION

IDAF mean scores on dental anxiety verified that the subjects in this study do have certain levels of dental anxiety as the mean score was above the cutoff score of 2.5 indicating presence of dental anxiety. However, the IDAF mean score on dental fear indicated that the subjects likely do not have dental phobia as the scores were below the cutoff score of 4.0 indicating dental phobia. Based on GAD mean score, the data suggests that the subjects enrolled so far exhibit mild signs for generalized anxiety as the mean score was above the cut off line of 5.

A noteworthy finding in the study despite the small sample size is that those patients who interacted with the therapy dogs are generally happy with the experience based on the high therapy satisfaction mean score which hovered near 37 where the highest possible satisfaction score was 40 for this measure.

Moreover, the most significant potential support for the efficacy of therapy dogs comes from the analysis of VAS mean scores. Based on VAS Comfort mean score, the subjects in DOG group reported higher level of comfort after the dental treatments than

SC group at both events. It is also notable that the level of comfort increased for DOG group at the second event whereas the level of comfort in SC group decreased during the same time span. VAS Anxiety mean score also tells the similar story. The level of anxiety for the DOG group is much lower by the difference of 30 points at T1 and 29 points at T2 when compared to the SC group at respective events.

It is important to reiterate that this is an interim data analysis based on very limited number of patients and therefore it is unrealistic at this point to draw a statistically significant result. However, the results suggest that the intervention with therapy dogs with adults are feasible and acceptable. Furthermore the data is definitely trending toward an encouraging direction for the study.

Study Limitations

During the recruitment process and the execution phase of the study, several possible limitations were noted. First, it was very difficult to recruit patients for the study. Also, many who had interest in the study did not require the minimum three dental treatment visits for their treatments. Another possible limitation is that the dog handlers were often different at times, which may elicit different behavior with from the dogs. However, substantial effort was made to use the same dog and the same handler for each encounter.

CONCLUSION

Despite the limited sample size for the study, early data analysis has shown that therapy dog intervention has the potential to be effective means to counter and aid patients struggling with dental anxiety without the use of pharmacological interventions. This can be particularly beneficial for those dentally anxious active duty patients to increase their availability for deployments without the risks of pharmacologic measures. This study may also prove to demonstrate the feasibility and the efficacy of therapy dogs to reduce anxiety in dental patients, which will improve the overall quality of life for patients and the overall quality of care for the dentists.

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