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

by

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A thesis submitted to the Faculty of the
Comprehensive Dentistry Graduate Program
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in partial fulfillment of the requirements for the degree of
Master of Science
in Oral Biology

June 2020

Naval Postgraduate Dental School
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Bethesda, Maryland

CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's thesis of

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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: An estimated 6-14% of the United States population avoid dental treatment due to anxiety. Avoidance of routine dental care can precipitate deteriorating oral health requiring more complex and expensive treatment. Options for management of dental anxiety include psychological and pharmacological therapies. Therapy dogs have been used to decrease dental anxiety in children. However, there is no current research on the impact of therapy dogs on adults with dental anxiety.

Objectives: 1) To assess the efficacy of a therapy dog intervention for dental anxiety on self-reported anxiety and comfort levels, 2) assess differences in physiological reactivity during dental care, and 3) explore associations among dental anxiety and physiological reactivity.

Methods: Subjects were adult patients with dental anxiety and were randomized into a therapy dog group (DOG) or standard control (SC) group. DOG group participants were exposed to a therapy dog for 10 minutes at start of two dental visits. SC subjects were treated routinely for two dental visits. Study outcomes included psychological (e.g., dental anxiety) and physiological (e.g., Heart Rate Variability (HRV)) assessments using a Firstbeat electrocardiogram device.

Results: In this ongoing study ($N=17$; 10 DOG, 7 SC), comfort level post-intervention was significantly different between groups ($p<0.05$) with higher comfort reported in the DOG group. There was no difference in anxiety level after the intervention or between visits ($p>0.05$). During the intervention, participants in the DOG group evidenced significantly higher HRV ($p<0.05$), but this difference was not found during the dental procedure. There was no significant association between dental anxiety score and physiological reactivity in either group.

Conclusions: Therapy dog intervention may be effective in increasing comfort levels, and participants were very satisfied with the intervention. Therapy dog intervention shows promise as an alternative therapy in the management of adults with dental anxiety allowing them to pursue routine dental care.

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LIST OF ABBREVIATIONS

Abbreviation	
AAT	Animal-Assisted Therapy
AEGD	Advanced Education in General Dentistry
CBT	Cognitive Behavioral Therapy
CDAS	Corah’s Dental Anxiety Scale
DHQ	Dental Health Questionnaire
ECG	Electrocardiographic
GAD	Generalized Anxiety Disorder
HF	High Frequency
HIPAA	Health Insurance Portability and Accountability Act
HRV	Heart Rate Variability
IDAF-4C	Index of Dental Anxiety and Fear
IRB	Institutional Review Board
IVCS	Intravenous Conscience Sedation
LF	Low Frequency
MDAS	Modified Dental Anxiety Scale
NPDS	Naval Postgraduate Dental School
OHIP	Oral Health Impact Profile
PHQ	Patient Health Questionnaire
RMSSD	Root Mean Square of the Successive Differences
SC	Standard Care
TSS	Therapy Satisfaction Scale
VAS	Visual Analog Scale

Review of the Literature

What is Dental Anxiety

While anxiety and fear are related, they are in fact different. "Anxiety is an emotional state which precedes an encounter with a feared object or situation, whereas fear refers to the actual, or 'activated' response to the object or situation." (Armfield and Heaton, 2013, pg. 391) When you apply these definitions to dentistry, dental anxiety is the response patients will have while thinking of dental appointments or procedures. Dental fear is the physiologic 'fight or flight' response patients have during dental visits (Malamed, 2018). The physiologic responses to dental anxiety can include but are not limited to tachycardia, perspiration, hyperventilation, hypertension, muscle tightening, shaking and other behavioral movements (Malamed, 2018).

Prevalence and Impact of Dental Anxiety

It is estimated that between 6% to 14% of the population in the United States avoid dental treatment due to fear and anxiety (Malamed, 2018). In a 2009 United Kingdom survey, it was found that 49% of the population reported having dental anxiety and 12% reported having high dental anxiety (Hill et al., 2013). Armfield found that high dental fear affects one in six Australians or approximately 16% of the adult population (Armfield and Heaton, 2013). This is true for most Western countries around the world (Carter et al., 2014). Consistently these studies find there is a higher prevalence of dental anxiety in females compared to males, with 20% reporting dental anxiety compared to 12% (Armfield et at., 2006). Age is also a consideration, with the highest prevalence of dental anxiety occurring in adults ages 35-44 (19.7%) and ages 18-34 (15.1%) (Armfield et al., 2006).

Many patients with dental anxiety will avoid dental visits or cancel appointments until they experience severe pain (Appukuttan, 2016). It has been shown that both adult and children with dental anxiety are more difficult for the dentist to treat and require more time in the dental chair. This is usually due to their extensive treatment needs, pain, and possibly even their behavior during the visit. (Armfield and Heaton, 2013) Eventually this can lead to a cycle of avoiding routine dental care until it becomes painful throughout the patient's life (Armfield, 2010).

Etiology

Dental anxiety and fear can impact patients' daily lives, through discomfort from dental pain or embarrassment from poor oral health. Dental fear and anxiety are most likely produced from multiple pathways including both psychological and physiological and could possibly have a genetic component (Carter et al., 2014 and Beaton et al., 2014).

Physiological sources of dental anxiety are usually linked to a history of stressful dental experiences (Humphries et al., 2011). These experiences can be connected to experiences as either a child or an adult (Beaton et al., 2014). This is also referred to as a conditioning pathway; where a patient learns from personal experience that experiences have unpleasant outcomes. This appears to be the most common way patients develop dental anxiety. (Carter et al., 2014)

Children can also develop dental anxiety as a learned response to a parent, siblings, friends, teacher or even the negative view the media can have towards dental visits. One study reported that 56% of patients that reported high dental anxiety also had a family member who suffered from dental anxiety. (Beaton et al., 2014) Another psychological source is through verbal threats. In this pathway, an influential adult in the child's life threatens the child with a

"painful experience" as punishment which in the case of dental fear and anxiety is linked to a dental visit (Carter et al., 2014).

Other studies have hypothesized a genetic component of dental anxiety based on the idea that one might inherit vulnerabilities that can increase the probability they will have anxiety (Carter et al., 2014 and Beaton et al., 2014). One study involving twins found a genetic component to dental anxiety which is stronger in females than males (Ray et al., 2010).

Patients might also have anxiety related to one specific aspect of the dental visit. Specifically, a person's fear of choking or gagging, fear of local anesthetic injections or that the local anesthetic will not be enough, and they will still feel pain can all produce dental anxiety. Other's may have anxiety due to their perceived lack of control during the dental visit (Armfield and Heaton, 2013).

Identification and Assessment

Identification of patients with dental anxiety is imperative in the successful treatment of the patient (Armfield and Heaton, 2013). Initial interaction with patients is the ideal time to identify dental anxiety through generalized questions regarding chief complaints, previous dental experiences, and expectations. Patients can be identified and assessed through direct observation, self-reporting questionnaires, and physiologic measures (Appukuttan, 2016).

Signs of dental anxiety that can be assessed through direct observation during treatment include trembling, diaphoresis, stiff posture, clenching of hands or dental chair, or apparent unease (Henry et al., 2018). However, chairside assessment through direct observation may not be accurate or effective in managing dental anxiety (Armfield and Heaton, 2013). Heaton and colleagues found that assessment by the dentist using direct observation only had moderate

correlation with self-report data and found self-report data to be an accurate predictor of dental anxiety (Heaton et al., 2007).

There are several self-reporting questionnaires available, the most common are Corah's Dental Anxiety Scale (CDAS), Modified Dental Anxiety Scale (MDAS), Visual Analog Scale (VAS) (Appukuttan, 2016), and Index of Dental Anxiety and Fear (IDAF-4C) (Armfield and Heaton, 2013). The CDAS is one of the most widely used measures that was originally created in the 1960's and consists of four questions about different dental situations (Appukuttan, 2016). The MDAS is a modified version of the CDAS by Humphris that includes a specific question relating to dental anesthetic (Humphris et al., 1995). The IDAF-4C shows advantage over other scales due to its able to assess the complex nature of dental anxiety (Armfield, 2010).

The IDAF -4C 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. While this scale is used to assess dental fear and anxiety it also includes questions regarding the most common fearful events that occur during dental treatment. This information can be useful in identifying the level of dental anxiety, the presence of any triggers and how the dentist could reduce some anxiety (Armfield, 2010).

Results of these questionnaires will allow the provider to assess the level of dental anxiety (mild, moderate, extreme) in patients (Appukuttan, 2016). Despite the availability of dental anxiety questionnaires, most dental practices do not utilize them, in fact one study found that only 20% of practices have the questionnaires available (Dailey et al., 2001).

Methods to quantify the physiologic manifestation of dental anxiety include monitoring blood pressure, pulse rate, pulse oximetry, finger temperature and galvanic skin response (Appukuttan, 2016). Additionally, heart rate variability (HRV) has been used to evaluate both psychological and physiological disorders. It has been shown to be an effective and non-invasive way to evaluate the body's reaction to stress (Teisala et al., 2014).

Both the sympathetic and parasympathetic nervous system influence heart rate and rhythm. Heart rate is continuously adjusting based on our daily activities, meaning heart rate is constantly changing (Hamilton and Alloy, 2016). Heart rate variability measures the variations between heart rates as well as intervals between consecutive heart beats. Monitoring heart rate and HRV is a noninvasive way to measure the autonomic nervous system. Heart rate variability changes during the shift from parasympathetic influences to sympathetic influences is an important measure of the body's ability to react to stress (Hamilton and Alloy, 2016). People with lower HRV have been found to have poor emotional regulation which can be associated with symptoms of depression (Hamilton an Alloy, 2016).

Time-based measures are used when analyzing HRV data and are often considered the simplest measure (Task Force, 1996). With time-based measures, the heart rate is recorded with an electrocardiogram (ECG) and the normal interval between heart beats can be analyzed; this is referred to as the NN interval (Task Force, 1996). The root mean square of the successive differences (RMSSD) of the NN interval is an accurate way to evaluate the strength of the parasympathetic branch of the autonomic nervous system (Task Force, 1996). When people are relaxed, there is an increase in the parasympathetic nervous system influence on the body, heart rate will decrease and HRV will increase. During times of stress or anxiety, there is an increase

in the sympathetic nervous system influence causing heart rate to increase and HRV to decrease. (Task Force, 1996)

Frequency-based measures are also used when analyzing HRV data. High frequency (HF) HRV reflect parasympathetic influences and low frequency (LF) HRV reflects sympathetic influences (Hamilton and Alloy, 2016). Frequency-based measures use a ratio of LF to HF HRV where unlike time-based measures, higher values indicate more sympathetic activity (Task Force, 1996).

Treatment Options

Treatment options vary depending on the severity of dental anxiety the patient experiences. Many patients with mild dental anxiety can be treated with only minor treatment modifications. These modifications usually center around forming a trusting relationship between the patient and dental team as well as allowing the patient to maintain control throughout the procedure. Effectively communicating the treatment plan by providing information on what the patient might see, feel or hear and then allowing the patient to ask questions prior to the start of treatment can help manage mild dental anxiety. Simply allowing the patient to raise a hand if experiencing any discomfort or concerns allows the patient to feel like they have control and can reduce anxiety (Armfield and Heaton, 2013).

Patients with moderate to severe dental anxiety may need to be managed with additional resources. Cognitive behavioral therapy (CBT) is the most accepted psychological treatment for anxiety's related disorders (Appukuttan, 2016). Cognitive behavioral therapy is a short-term therapy that is the combination of behavior therapy and cognitive therapy (Newton et al., 2012). During CBT, patients are able to learn skills to change negative thoughts and behaviors allowing

them to manage their anxiety through goal-oriented sessions with a qualified provider (Appukuttan, 2016). For example, patients may learn relaxation skills through breathing exercises or muscle relaxation in combination with identifying fearful thoughts they might experience when thinking of dental visits and restructure those thoughts and replace them with more realistic and less fearful thoughts (Armfield and Heaton, 2013).

For patients with urgent treatment needs, severe dental anxiety, or are unwilling to undergo psychological treatment, pharmacological management maybe indicated (Appukuttan, 2016; Armfield and Heaton, 2013). Minimal sedation/ anxiolysis can be used to manage patients with mild to moderate dental anxiety (Malamed, 2018). Nitrous oxide sedation or oral benzodiazepines are typically used for minimal sedation (Malamed, 2018).

For patients with moderate to severe dental anxiety, moderate sedation using intravenous conscience sedation (IVCS) is recommended (Malamed, 2018). IVCS typically involves the use of benzodiazepines alone or can be combined with an opioid (Malamed, 2018).

In certain cases, a patient might have dental anxiety so severe that they are unable to be treated safely without the use of general anesthesia. Dental procedures under general anesthesia should in most cases be considered the last resort since it does not help the patient manage or help reduce their dental anxiety (Armfield and Heaton, 2013).

Animal-Assisted Therapy

One treatment option that is showing promise in the reduction of general anxiety and fear is the use of animal-assisted therapy (AAT). The idea of using animals to improve the emotional well-being of patients is well-established and studies have shown AAT to have a positive physical, psychological and emotional impact on patients (Cole et al., 2007). According to the

American Veterinary Medical Association, AAT "is a goal directed intervention in which an animal meeting a specific criteria is an integral part of the treatment process. It is designed to promote improvement in human physical, social, emotional, or cognitive function" (American Veterinary Medical Association Definitions, 2020).

Animal-assisted therapy has been shown to have both subjective and objective benefits for humans (Marcus, 2013). The use of therapy dogs has been shown to reduce in the stress hormones epinephrine and norepinephrine, increase endorphins (Odendaal and Meintjes, 2003), as well as increase the pain threshold (Marcus et al., 2012). Therapy dogs have been found to have a greater impact on lowering cortisol levels and heart rate prior to a stressful event compared to human social support (Polheber and Matchock, 2014). Studies utilizing self-report data has shown a decrease in the anxiety levels after just one AAT session of less than twenty minutes duration (Cole et al., 2007 and Grajfoner et al., 2017).

To the author's knowledge, no prior studies have evaluated the efficacy of AAT on adult patients with dental anxiety prior to undergoing dental treatment. The aims of the current study are to determine to assess the efficacy of a therapy dog intervention for dental anxiety on self-reported anxiety and comfort levels, assess differences in physiological reactivity during dental care, and explore associations among dental anxiety and physiological reactivity.

Materials and Methods

This study was reviewed and approved by the Walter Reed National Military Medical Center Institutional Review Board, IRB # WRNMMC-2016-0016.

Participants:

Study participants were patients treated by residents enrolled in either the Naval Postgraduate Dental School's (NPDS) two-year Advanced Education in General Dentistry (AEGD) training program or one-year AEGD training 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.

A 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 were met. Inclusion criteria were age $\geq$ 18 years with dental anxiety, generalized or situational anxiety, and required at least three separate dental appointments. Exclusion criteria included fear of dogs, dislike of dogs, severe dog allergy, pregnant or breastfeeding women, history of schizophrenia or other chronic psychotic disorders, and acute psychiatric symptoms that impair ability to function in non-psychiatric setting. If the potential study patient met all criteria and was interested in study participation, Informed Consent was reviewed and signed by the study participant.

Study participants were randomly assigned to either the intervention (DOG) group or 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: (Figure 1)

Written informed consent was obtained from eligible patients during the patient screening visit in accordance with IRB/HIPAA guidelines. After consent and the Demographics Questionnaire (Appendix A) was completed, each participant completed the Generalized Anxiety and Patient Health Questionnaire (Appendix B), Oral Health Impact Profile (Appendix C), and Index of Dental Anxiety and Fear-4C (IDAF-4C, Appendix D) 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 during 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 dental treatment room, the Bodyguard Heart Rate device (Firstbeat Technologies, Ltd, Jyvaskyla, Finland) 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-4C (IDAF-4C). Each participant also completed the study Visual Analog Scale (VAS, Appendix E), 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, Appendix F).

The final study session (dental visit 3) for participants in the DOG group began with the completion of the 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 the completion of all dental procedures, the participant completed the VAS and the TSS. 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 a 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 TSS. At this point, the participant was released from the study and thanked for participating. Any miscellaneous provider and handler notes were documented.

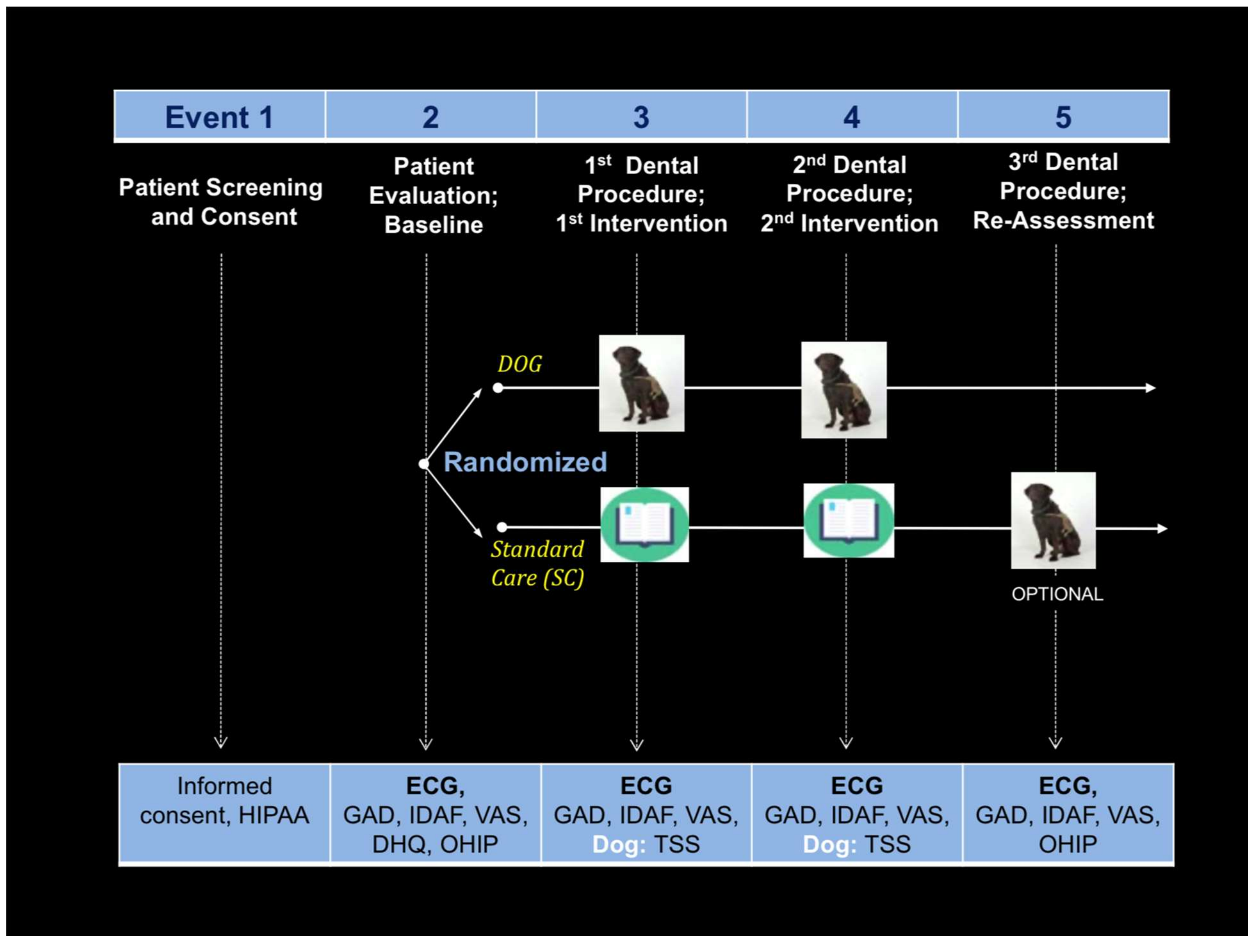

Figure 1. Recruitment, Intervention and Assessment Timeline

Event Details:

1. Patients were screened for the study.
    a. Patients who met inclusion and exclusion criteria were offered to complete consent.
2. Participants met with their assigned residents to develop a treatment plan and complete baseline assessment.
    a. Baseline assessment included self-report measures and resting ECG using a Firstbeat Bodyguard devices.

   b. After assessment, participants were randomly assigned to DOG or SC groups.

3. Participants in the DOG group were introduced to the dog and spent 10 minutes with dog in operatory prior to dental treatment. Participants in the SC group spent 10 minutes in the operatory quietly resting (reading magazines, etc.) prior to dental treatment.
   a. Participants in both groups competed self-report measures before and after intervention and after dental treatment (Figure 1).
4. Participants in the DOG group had a second exposure to the therapy dog prior to their second dental treatment visit. Assessments for both groups were as described in #3 above.
5. At the third appointment, all participants repeated baseline assessment. Participants in the SC groups were provided with the dog intervention.

Intervention details:

DOG group. Study participants assigned to the DOG group spent 10 minutes with the dog, 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 scheduled 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 10 minutes, the dog handler reported what specific type of interaction occurred between the participant and therapy dog. Due to the 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 may 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 begin 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 according to the treatment plan. At Event 5, the SC group participants were offered the opportunity to interact with a therapy dog, following the same procedures as the DOG group participants as noted Events 3 and 4.

Psychological and Physiological Assessment

Assessments for this study included self-report measures and heart rate. To record heart rate (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 participants 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 45 minutes into the dental visit.

Self-report measures

All patients completed the following self-report measures. Please see Figure 1 for details on frequency of each self-report measure. All self-report measures are included in the Appendices (B-F).

Pre-consent screening:

At the initial visit and prior to obtaining informed 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.

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 and validity and has been translated into many languages and used clinically throughout the world (Slade, 1997).

Generalized Anxiety Disorder GAD-7:

The GAD-7 (Spitzer et al., 2006) is a 7-item measure used to assess presence of symptoms of generalized anxiety over the previous two weeks. Spitzer and colleagues, showed that 89% of patients with GAD scored >10. The GAD-7 is a widely used assessment instrument and has demonstrated good psychometric properties in clinical and research applications (Spitzer, Kroenke et al., 2006).

Patient Health Questionnaire-9 (PHQ-9):

The PHQ-9 (Kroenke et al., 2001) is a 9-item measure of the presence and severity of depressive symptoms over the previous two weeks. Mild, moderate, moderately severe and severe symptoms are reflected in scores of 5, 10, 15, and 20, respectively. 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 were 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 (Oei and Shuttlewood, 1999).

Physiological Measures

All the patients were assessed physiologically using heart rate variability recorded with the Bodyguard Heart Rate device. 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 ECG. This device is smaller than traditional Holter monitors, easy to connect and uses two disposable surface electrodes. The Bodyguard has been used for 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 were 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 root mean square of the successive differences of the NN intervals (RMSSD) 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:

This is a pilot study with 34 evaluable subjects (17 in each group), requesting to enroll up to 44 participants to account for attrition. This number will assess the feasibility of both the dog exposure treatment and the physiological measurements. This number of subjects likely does not provide adequate power to address all aims but will provide future studies with important data concerning the intervention's anticipated effect 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 17 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. 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.
4. **Specific Aim 1.** The efficacy of the therapy dog intervention will be evaluated by reporting and comparing post-treatment VAS scores for both comfort and anxiety levels between the intervention and control group. We expect that patients in the intervention group to report higher comfort and lower anxiety post-treatment, compared to patients in the control group.
5. **Specific Aim 2.** The efficacy of therapy dog intervention will also be evaluated by analyzing heart rate variability during the intervention/control period and during the first 45 minutes of dental treatment. We expect the patients in the intervention group to exhibit higher heart rate variability (lower frequency-based HRV) during both the intervention/control period and during dental treatment, compared to patients in the control group.
6. **Specific Aim 3.** We will explore the associations among patient-reported dental anxiety, generalized anxiety, depression, and heart rate variability. We expect that patients with higher levels of dental anxiety will exhibit lower heart rate variability during dental treatment, however this relationship maybe mediated by generalized anxiety and/or symptoms of depression.

Results

This ongoing study was started in April 2017 with a goal enrollment of 44. To date we have seventeen (n=17) participants who have completed this study, with ten randomly assigned to the DOG group and seven assigned to the SC group. There are currently two participants who are enrolled but have not yet completed all scheduled visits. There has also be five participants who have dropped from the study due to reasons outside of our control, including permanent change of station orders or patients retiring from active duty and leaving the local area. Of the 17 participants who have completed the study, 14 (82%) are female and 3 (18%) are male. The age of the participants ranges from 19-51 (SD=10.4) years of age with a mean age of 33.3 years. For all participants, both self-report questionnaires and HRV have been analyzed. The interventions or events 3 and 4 have been labeled dental visit 1 and dental visit 2 respectively.

The analysis of the Index of Dental Anxiety and Fear-4C scores for dental visit 1 and 2 is shown in Figure 2. Participants in the SC group (n=7) had a mean score (standard deviation) of 3.48 (0.7) at dental visit 1 and 3.52 (0.9) at dental visit 2. For the DOG group (n=10), scores were 3.89 (1.1) at dental visit 1 and 3.52 (1.3) at dental visit 2. These differences between the groups were not statistically significant (p-value>0.05) at either visit (p=0.401) for dental visit 1 and (p=0.956) at dental visit 2.

The IDAF-4C also gives us scores for the most common dental anxiety triggers, Figure 3 shows the highest scores at dental visit 1. For the SC group (scores$\geq$ 2.5), pain 4.43 (0.8), lack of control 3.57 (1.6), not knowing 3.14 (1.5), needles 3.86 (1.7), and gagging/choking 3.00 (1.7). For the DOG group, the highest scores at dental visit 1 (scores$\geq$ 2.5) were pain 4.00 (1.3), embarrassed 2.80 (1.8), lack of control 3.30 (1.7), needles 3.10 (1.6), gagging/choking 2.70 (1.6),

and unkind dentist 3.20 (1.9). There was no statistically significant difference (all p-values > 0.05) between the groups at dental visit 1.

For dental visit 2, dental anxiety triggers are shown in Figure 4, with the highest scores reported for the SC group (scores$\geq$ 2.5) were pain 4.14 (1.1), lack of control 3.57 (1.4), numbness 2.80 (1.4), not knowing 3.00 (1.3), needles 3.40 (1.6) and unkind dentist 3.00 (1.0). For the DOG group, the highest scores reported at dental visit 2 (scores$\geq$ 2.5) were pain 3.70 (1.6), embarrassed 2.50 (1.9), lack of control 3.20 (1.6), needles 2.60 (1.8), gagging/choking 2.70 (1.5), and unkind dentist 3.20 (1.9). There was no statistically significant difference (all p-values >0.05) between the groups at dental visit 2.

For the DOG group, dental anxiety triggers from dental visit 1 and 2 were compared (Table 1). There was no statistically significant difference (all p-values > 0.05) found in the dental anxiety triggers between the visits. Dental anxiety triggers from dental visit 1 and 2 were compared for the SC group (Table 2), there was a statistically significant difference found in the anxiety trigger for numbness (p=0.045, F= 6.53).

Oral health impact profile (OHIP-14) self-report questionnaire, assessing the social and psychological impact of oral health on general well- being data analysis is still ongoing and will be presented in future research.

General anxiety disorder (GAD-7) self-report questionnaire, assessing patients for general anxiety disorder over the previous two weeks, results are shown in Table 3. Mean scores for both groups at dental visit 1 and 2 are less than 10. Patient health questionnaire (PHQ-9) scores (Table 4), for the DOG group were 8.0 (8.5) and 7.3 (8.0) and for the SC groups were 7.1 (7.7) and 4.1 (3.6) at dental visit 1 and 2, respectively.

Visual Analog Scales (VAS) were completed for anxiety and comfort at the completion of each dental visit for both groups (Figure 5 and 6). The mean level of anxiety for the SC group at dental visit 1 was 4.2 (1.6) and at dental visit 2 was 5.2 (1.9). For the DOG group the mean reported level of anxiety was 3.5 (2.2) at dental visit 1 and 3.8 (2.5) at dental visit 2. The VAS for current level of anxiety after treatment showed no statistically significant difference between the groups for dental visit 1 (p=0.432) or dental visit 2 (p=0.214).

The mean level of comfort for the SC group at dental visit 1 was 5.4 (2.3) and at dental visit 2 was 5.1 (1.0). For the DOG group the mean reported level of anxiety was 6.9 (2.2) at dental visit 1 and 6.9 (2.0) at dental visit 2. The VAS for current level of anxiety after treatment showed no statistically significant difference between the groups for dental visit 1 (p=0.184). There was a statistically significant difference between groups for dental visit 2 (p=0.031).

The Therapy Satisfactions Survey (TSS) was completed by participants in the DOG group at the end of dental visits 1 and 2 (Figure 7). This survey has a scale of 0-35 with higher scores signifying higher satisfaction levels. For dental visits 1 and 2 the mean scores reported were 33.8 (3.8) and 34.7 (4.3), respectively. These high scores suggest all participants in the DOG group were highly satisfied with the therapy dog intervention.

Each participant was assessed physiologically using Heart Rate Variability (HRV) recorded with a portable heart rate monitor. HRV presented here as a ratio of the Low Frequency (LF) HRV to the High Frequency (HF) HRV (LF/HF) or frequency domain. The HRV data was analyzed for two separate time periods, during the intervention and during the first 45 minutes of the dental procedure.

At dental visit 1, the mean frequency domain HRV during the intervention for the SC group was 1.3 (0.7) and for the DOG group the frequency domain HRV was 4.56 (2.8). At dental visit 2 the mean HRV during the intervention was 2.43 (3.2) for the SC group and 3.83 (1.8) for the DOG group. During the intervention, participants in the DOG group had a significantly higher frequency domain HRV (p=0.008) at dental visit 1. No significant difference was noted in HRV at the dental visit 2 (p=0.284) (Figure 8).

At dental visit 1, the mean frequency domain HRV during the procedure for the SC group was 1.82 (0.7) and for the DOG group the frequency domain HRV was 2.48 (0.7). At dental visit 2 the mean HRV during the intervention was 1.78 (1.0) for the SC group and 2.52 (0.8) for the DOG group. During the first 45 minutes of the dental procedure, neither group showed a significantly different frequency domain HRV, (p=0.278) at dental visit 1 or at dental visit 2 (p=0.124) (Figure 9).

Root mean square of successive differences in NN interval (RMSSD) was used to analyze time domain HRV during both the intervention and procedure at dental visits 1 and 2 for each group (Table 5). At dental visit 1, the mean time domain HRV during the intervention for the SC group was 42.04 (17.4) and for the DOG group the time domain HRV was 38.03 (9.7). At dental visit 2 the mean HRV during the intervention was 29.83 (18.3) for the SC group and 39.14 (20.6) for the DOG group. During the intervention, neither group had a significantly different time domain HRV (p=0.568) at dental visit 1 or at dental visit 2 (p=0.388)

At dental visit 1, RMSSD during the procedure for the SC group was 40.26 (23.1) and for the DOG group the time domain HRV was 38.2 (15.8). At dental visit 2 the mean RMSSD during the intervention was 33.56 (20.7) for the SC group and 41.98 (16.6) for the DOG group.

During the first 45 minutes of the dental procedure, neither group showed a significantly different time domain HRV, (p=0.83) at dental visit 1 or at dental visit 2 (p=0.397).

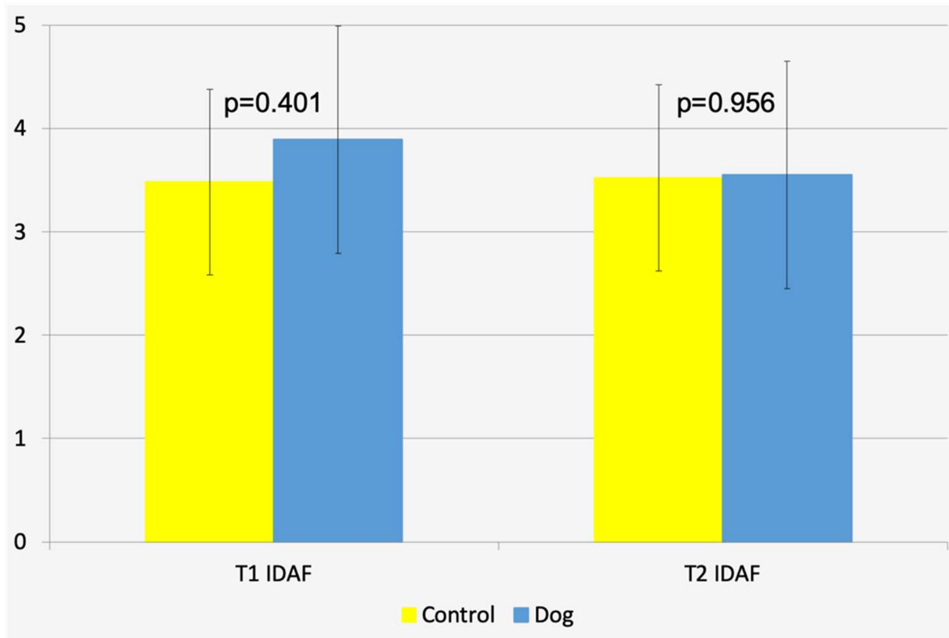

Figure 2. Index of Dental Anxiety and Fear-4C mean (and standard deviation) dental anxiety scores by group. A 5-point scale is used with scores $\geq$ 2.5 reflecting high dental anxiety and fear.

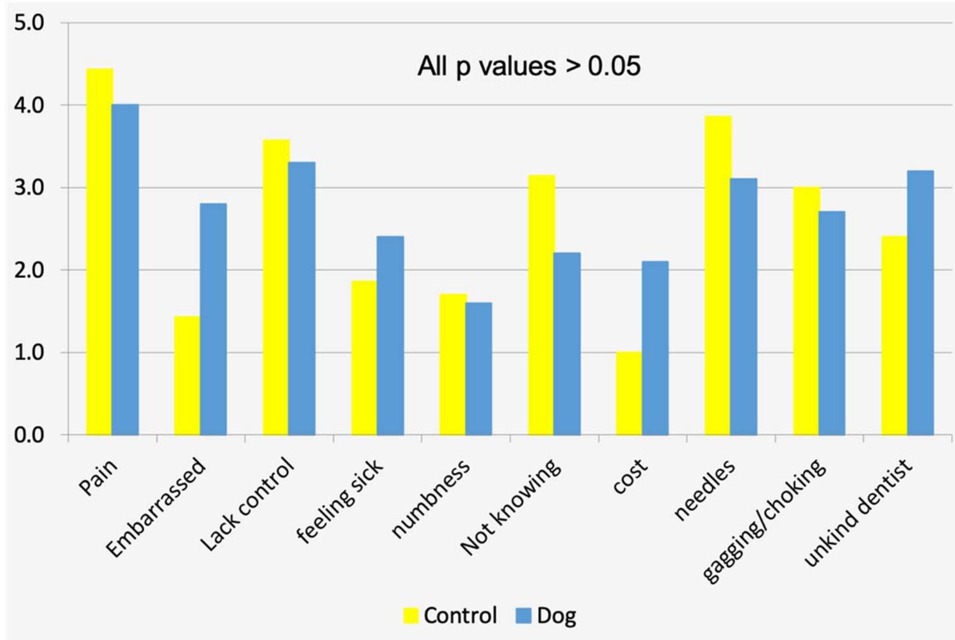

Figure 3. IDAF-4C mean scores for 10 most common dental anxiety triggers at dental visit 1 by groups.

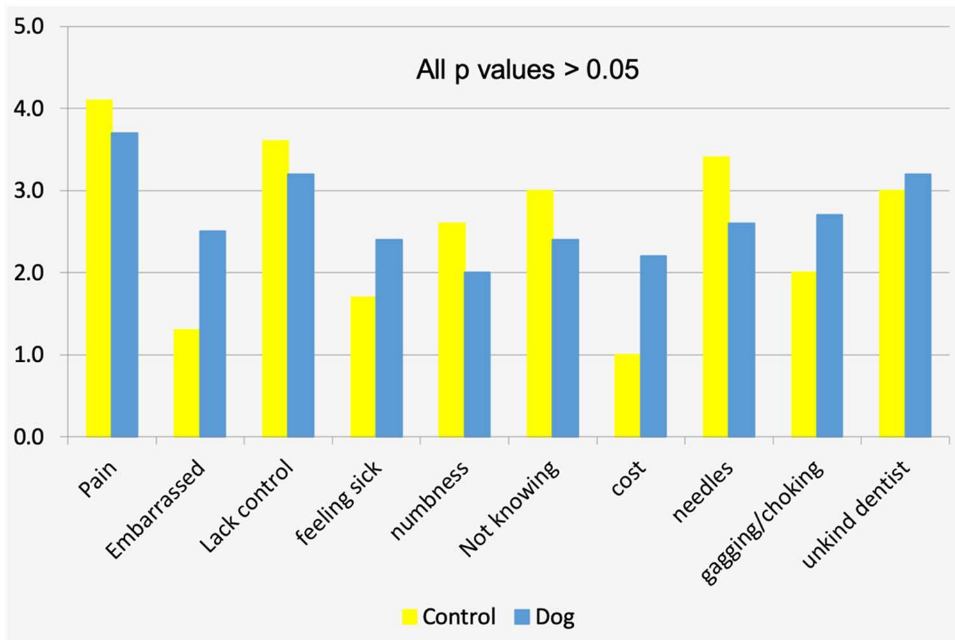

Figure 4. IDAF-4C mean scores for 10 most common dental anxiety triggers at dental visit 2 by group.

Table 1. *IDAF-4C dental anxiety triggers at dental visit 1 and 2, DOG group only. (Mean values (standard deviation). Ten most common dental anxiety triggers are evaluated in IDAF-4C.*

Dental Anxiety Trigger	Visit 1	Visit 2	F	*p* value
Pain	4.0 (1.3)	3.7 (1.6)	1.98	0.193
Embarrassed	2.8 (1.8)	2.5 (1.9)	0.67	0.434
Lack of control	3.3 (1.7)	3.2 (1.6)	0.06	0.811
Feeling sick or queasy	2.4 (1.4)	2.4 (1.2)	0.00	1
Numbness	1.6 (1.4)	2.0 (1.6)	3.27	0.104
Not knowing what dentist is doing	2.2 (1.6)	2.4 (1.6)	0.31	0.591
Cost	2.1 (1.8)	2.2 (1.8)	1.00	0.343
Needles/Injections	3.1 (1.6)	2.6 (1.8)	3.46	0.096
Gagging/Choking	2.7 (1.6)	2.7 (1.5)	0.00	1
Unkind or unsympathetic dentist	3.2 (1.9)	3.2 (1.9)	0.00	1

Table 2. *IDAF-4C dental anxiety triggers at dental visit 1 and 2, SC group only. (Mean values (standard deviation). Ten most common dental anxiety triggers are evaluated in IDAF-4C.*

Dental Anxiety Trigger	Visit 1	Visit 2	F	*p* Value
Pain	4.4 (0.8)	4.1 (1.1)	0.632	0.457
Embarrassed	1.4 (0.5)	1.3 (0.8)	0.300	0.604
Lack of control	3.6 (1.7)	3.6 (1.4)	0.000	1.000
Feeling sick or queasy	1.9 (1.5)	1.7 (0.8)	0.079	0.788
Numbness	1.7 (1.0)	2.8 (1.4)	6.53	0.045
Not knowing what dentist is doing	3.1 (1.5)	3.0 (1.3)	0.079	0.788
Cost	1.0 (0.1)	1.0 (0.3)	1.000	0.999
Needles/Injections	3.9 (1.7)	3.4 (1.6)	0.794	0.407
Gagging/Choking	3.0 (1.7)	2.0 (1.7)	5.25	0.062
Unkind or unsympathetic dentist	2.4 (1.5)	3.0 (1.0)	2.40	0.172

Table 3. *Generalized Anxiety Disorder-7 at both dental visits by group. Mean values (standard deviation). Scores of >10 reflect presence of symptoms of generalized anxiety over previous two weeks.*

Group	Visit 1	Visit 2	F	*p* value
Dog Group	8.7 (7.8)	8.0 (7.5)	0.846	0.382
Control Group	6.0 (4.4)	5.7 (2.6)	0.103	0.760

Table 4. *Patient Health Questionnaire-9 at both dental visits by group evaluating presence and severity of depression symptoms over previous two weeks. Mean values (standard deviation). Mild, moderate, moderately severe, and severe symptoms are reflected in scores of 5, 10, 15, 20, respectively.*

Group	Visit 1	Visit 2	F	*p* value
Dog Group	8.0 (8.5)	7.3 (8.0)	1.47	0.257
Control Group	7.1 (7.7)	4.1 (3.6)	3.20	0.124

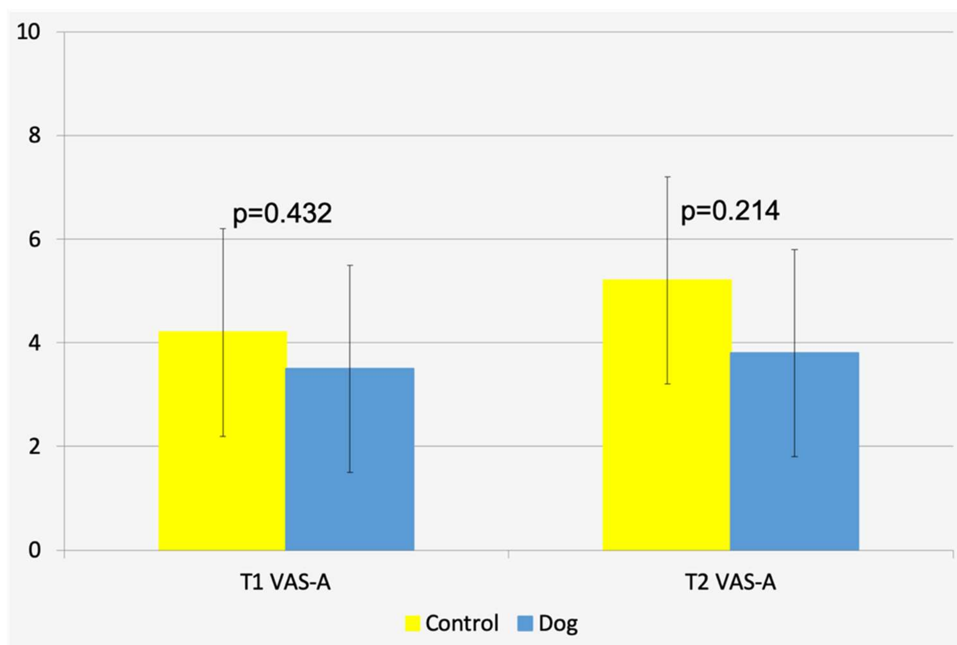

Figure 5. Visual Analog Scale for anxiety level. Mean (and standard deviation) scores for anxiety after procedure by group for both dental visits. Higher scores indicate greater anxiety.

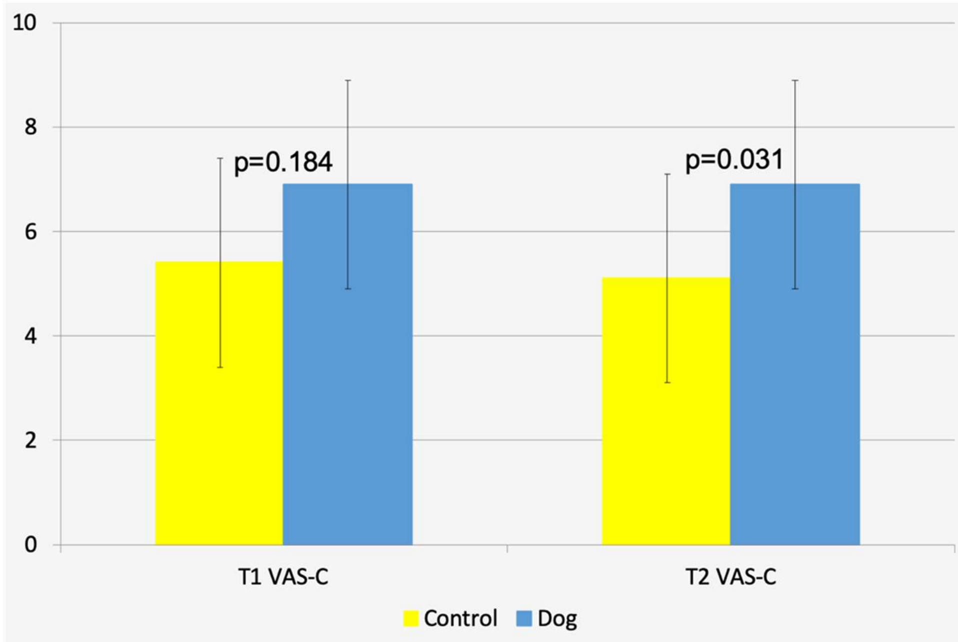

Figure 6. Visual Analog Scale for comfort level. Mean (and standard deviation) scores for comfort after procedure by group for both dental visits. Higher scores indicate greater comfort.

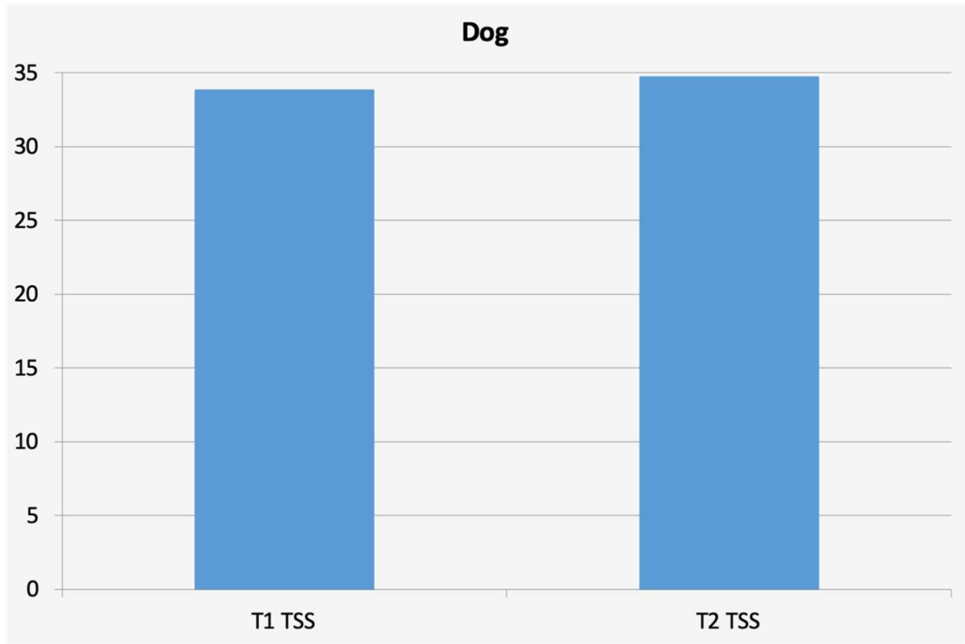

Figure 7. Therapy Satisfaction Scale at both dental visits for the DOG group only. Scores are based on 5-point scale with higher scores (35 maximum) indicating satisfaction in the animal-assisted therapy.

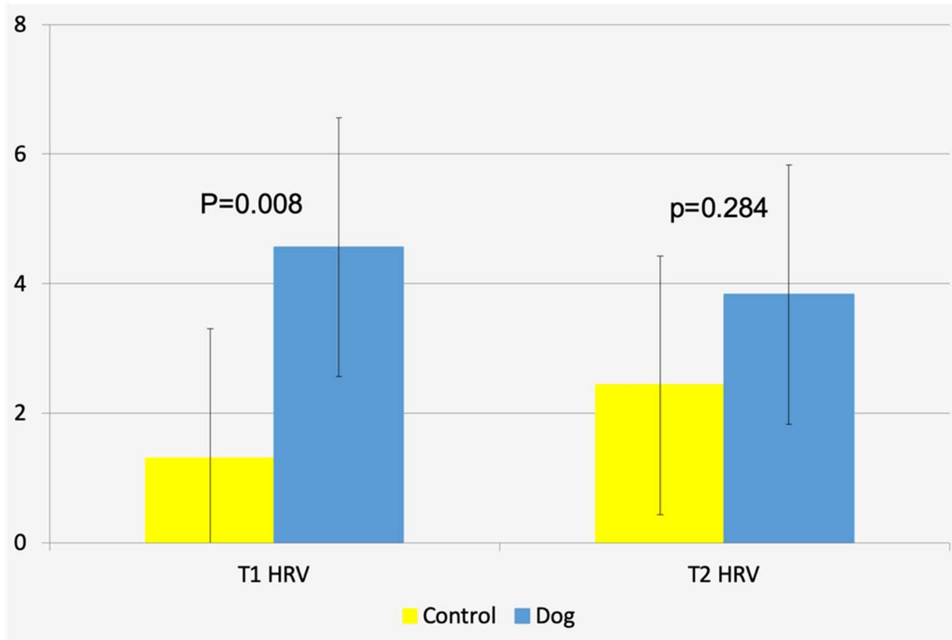

Figure 8. Heart rate variability (LF/HF) using frequency domain analysis during intervention for both dental visits mean (and standard deviation) scores by group. Higher scores indicate greater sympathetic nervous system activation.

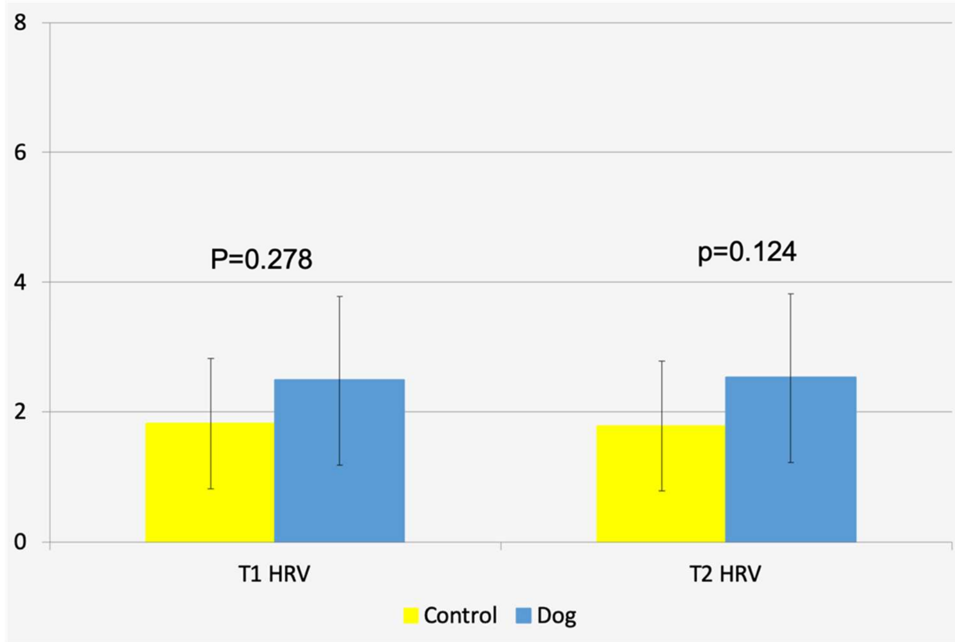

Figure 9. Heart rate variability (LF/HF) using frequency domain analysis during procedure for both dental visits mean (and standard deviation) scores by group. Higher scores indicate greater sympathetic nervous system activation.

Table 5: *Time domain analysis of HRV using RMSSD during Intervention and Procedure for each group at each visit. Higher scores indicate more parasympathetic nervous system activation. Mean values (standard deviation).*

Dental Visit	DOG	Control	F	*p* Value
Visit 1 Intervention	38.03 (9.7)	42.04 (17.4)	.343	0.568
Visit 2 Intervention	39.14 (20.6)	29.83 (18.3)	.799	0.388
Visit 1 Procedure	38.20 (15.8)	40.26 (23.1)	.048	0.830
Visit 2 Procedure	41.98 (16.6)	33.56 (20.7)	.766	0.397

Note. *RMSSD Root Mean Square of Successive Differences in NN Interval.*

Discussion

The results from the Index of Dental Anxiety and Fear-4C scores *(Figure 2),* confirm patients from the desired target population were recruited. The IDAF-4C will identify both level of dental anxiety and fear and determine if the patient should be considered to have dental phobia. A score of $\geq$2.5 indicates high dental anxiety and fear while a score of $\geq$ 4 indicates dental phobia (Armfield, 2010). At both dental visit 1 and 2, all participants had a dental anxiety and fear score above 2.5. This indicates that all study participants do, in fact, have dental anxiety.

The IDAF-4C allows the provider to determine not just the level of dental anxiety but also the possible stimuli that are present in the dental office that may act as triggers for each individual (Armfield, 2010). A 2015 study by Armfield and Ketting, examined factors most relevant in predicting dental avoidance in individuals with high dental anxiety. They identified cost, embarrassment, lack of trust in the dentist, pain and communication as the most relevant factors for avoidance (Armfield and Ketting, 2015). In the current study, we found the most notable triggers were pain, lack of control, not knowing, needles, and an unkind dentist. While there was no significant difference between the groups at either visit or when comparing dental visit 1 to dental visit 2 for the DOG group, there was a significant difference for the control group for numbness (p=0.045) between dental visit 1 and 2. Treatment provided is an important consideration when you look at the results for anxiety triggers. All patients have different potential triggers which will impact their anxiety levels differently at each appointment depending on treatment. When looking at individual dental triggers for the current study, the reported results for the DOG group had more individual triggers that either remained the same or decreased when compared to the control group. While this is not a significant change it is useful information to consider prior to treating anxious patients.

The first aim of this study was to assess the efficacy of a therapy dog intervention for dental anxiety by comparing self-reported VAS for anxiety and comfort levels. Grajfoner and colleagues found a decrease in the anxiety levels after just one animal-assisted therapy session (Grajfoner et al., 2017). In this current study we found no significant difference between groups in visual analog scale for anxiety after treatment. This could be attributed to the location of the interventions. Participants in this study have high dental anxiety and the animal-assisted therapy interventions are taking place in the dental treatment room where many of the anxiety inducing stimuli are present.

The results for the visual analog scale for comfort does show improvement in the DOG group compared to SC. Comfort level post-intervention was significantly different between groups at dental visit 2 (p=0.031) with lower comfort level reported in the control group at both visits. Additionally, the VAS for both anxiety and comfort were completed in this study after dental treatment was completed rather than after the intervention. Overall, study participants have been very satisfied with the intervention.

The second aim was to assess the differences in physiological reactivity during dental care using heart rate variability. In this study we used frequency-based measures when analyzing the HRV data. In frequency-based HRV a ratio of LF/HF HRV is used where higher values indicate more sympathetic activity. When people are relaxed, there is an increase in the parasympathetic nervous system influence on the body, high frequency HRV will increase. During times of stress or anxiety, there is an increase in the sympathetic nervous system influence causing low frequency HRV to increase (Hamilton and Alloy, 2017; Task Force, 1997). Thus, we expected the patients in the intervention group to exhibit a lower frequency-

based heart rate variability during both the intervention and during dental treatment, when compared to patients in the control group. However, this was not shown.

During the intervention, participants in the DOG group evidenced significantly higher frequency domain HRV (p=0.008). This could be attributed to the interaction with the dogs at the first visit causing an increase in the sympathetic influences and increasing low frequency HRV. We did expect to find a lower HRV during the procedure in the dog group, but no significant difference was found.

The third aim was to assess associations among dental anxiety, generalized anxiety, depression, and physiological reactivity. Dental anxiety is often found in patients with generalized anxiety disorder (Henry et al., 2018). Generalized anxiety and depression were assessed using the GAD and PHQ, respectively. In this study, the mean scores for GAD were not clinically significant for generalized anxiety disorder and patients on average had mild symptoms of depression in the two weeks prior to the dental visit. In this preliminary analysis, we were unable to find an association between level of dental anxiety and generalized anxiety or depression, but this will continue to be evaluated as the study continues. There was no significant association between dental anxiety score and physiological reactivity in either group however this will continue to be examined as this is an ongoing study.

This study is limited by the small sample size as we are only approximately halfway through the recruitment and completion goals. The study will continue to recruit and complete treatment on patients currently enrolled in the study. Additionally, there are many variables impacting dental anxiety on each visit, specifically the participants treatment needs and if they have any anxiety related triggers. Tuk and colleagues found higher anxiety scores were

associated with a history of negative experiences with injections compared to those without (Tuk et al., 2017). Both pain and needles were two of the more notable triggers in this study, but the type of dental treatment patients received during each visit was not controlled for in this study.

The difference in appointment duration also made it difficult to analyze the physiologic data. All appointment lengths varied, and it was decided to only analyze the first 45 minutes after the 10-minute intervention of the appointment. Patients can experience stress and anxiety at different times throughout the appointment depending on the procedure. For many patients, the local anesthetic injection itself and concern that it won't be sufficiently effective to relieve pain will increase their anxiety during the first 45 minutes of the appointment, but this may not be true for all patients and procedures.

Although the interventions were conducted in the dental treatment room, infection control measure were considered. All facility dogs that are used as therapy dogs in this study have a strict grooming protocol that allows them to visit all areas of the medical treatment facility including areas where patients are immunocompromised. When both the therapy dogs and handlers are in the dental treatment room all instruments remained either covered or unopened in the sterilized packs. Due to infection control protocols for personal protective equipment, therapy dogs are not allowed in dental treatment rooms during dental procedures.

Conclusion

In conclusion, based on this interim analysis of an ongoing study, therapy dog intervention at this point does not appear to have a physiologic effect on adults with dental anxiety. The analysis of the physiologic HRV data did not show a reduction in the sympathetic nervous system influence during dental treatment. However, therapy dog intervention may be effective in increasing comfort levels, and overall participants were very satisfied with the intervention. With this increase in comfort and satisfaction, patients were willing to continue with the planned treatment and hopefully will pursue routine dental care in the future, rather than only addressing urgent dental needs. Therapy dog intervention shows promise as an alternative therapy in the management of adults with dental anxiety.

Appendix A

Demographics

1. **What is your gender?** ☐1 Male ☐2 Female
2. **What is your date of birth?** ___ ___ / ___ ___ / ___ ___ ___ ___
   Month *Day* *Year*

3. **What is your current age?** ______

4. **What is your height and weight?** ______ feet _____ inches ______ pounds

5. **Do you consider yourself to be of Latin or Hispanic origin?**
   ☐1 Yes

   ☐2 No

6. **What is your race/ethnicity?** (check all that apply)

   ☐1 White/Caucasian

   ☐2 Black/African American

   ☐3 American Indian or Alaska Native

   ☐4 Asian

   ☐5 Native Hawaiian or Other Pacific Islander

   ☐6 Other (specify): ____________________________

7. **Are you…** (check one)

   ☐1 Currently married

   ☐2 Currently living with partner

   ☐3 Separated

   ☐4 Divorced

   ☐5 Widowed

   ☐6 Never married

8. **What is your current employment situation?** (check all that apply)
   ☐Working: ☐1 Full time at job ☐2 Part time at job

   ☐ On Leave: ☐3 On leave with pay ☐4 On leave without pay

☐ Not employed:	☐5 Seeking work	☐8 Not seeking work
	☐6 Receiving disability	☐9 Not self-supporting
	☐7 Homemaker	☐10 Retired
☐ Student:	☐11 Full time	☐12 Part time

9. **What was the highest grade of school that you completed?**

☐1 Less than 8th grade

☐2 8th to 11th grades

☐3 High school graduate or equivalent (GED)

☐4 Technical or vocational school

☐5 Some college

☐6 College graduate

☐7 Post-graduate degree

10. **Have you taken any medications or natural supplements in the past 2 weeks?**

☐1 Yes IF **YES**, Please specify below.

☐2 No IF **NO**, Skip to **14**.

	Drug/Supplement	Dose	Since
(Pain)	________________	________________	________________
(Sleep)	________________	________________	________________
(Heart)	________________	________________	________________
(Birth Control)	________________	________________	________________
(Hormones)	________________	________________	________________
(Other)	________________	________________	________________
(Other)	________________	________________	________________

11. **Males skip to 16: How would you characterize your menstrual status during the last 12 months?**

☐1 Still having periods and not going through menopause

☐2 Still having periods but possibly going through menopause

☐3 Still having periods and on hormone replacement therapy

☐4 Going through menopause

☐5 Postmenopausal (no periods for at least 1 year)

☐6 Was pregnant

☐7 Other (please specify): ________________________

☐8 Don't know

12. **When was your last menstrual period? (check one)**

☐1 1-7 days ago

☐2 8-14 days ago

☐3 15-21 days ago

☐4 22-35 days ago

☐5 More than 35 days ago

☐6 My menstrual periods have stopped (no periods for at least 1 year)

13. **Have you had surgery before?** ☐1 Yes ☐2 N

If yes, when? Date(s) For what?

Date(s)	For what?

14. **Have you ever had a disease lasting longer than 2 months?** ☐1 Yes ☐2 No

If yes, when? Date(s) For what?

Date(s)	For what?

Appendix B

Generalized Anxiety and Patient Health Questionnaire

Over the last two weeks, how often have you been bothered by the following problems?

	Not at all	Several Days	Over Half the Days	Nearly Every Day
Feeling nervous, anxious, or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3
Worrying too much about different things	0	1	2	3
Trouble relaxing	0	1	2	3
Being so restless that it's hard to sit still	0	1	2	3
Becoming easily annoyed or irritable	0	1	2	3
Feeling afraid as if something awful might happen	0	1	2	3
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed, or hopeless	0	1	2	3
Trouble falling or staying asleep, or sleeping too much	0	1	2	3
Feeling tired or having little energy	0	1	2	3
Poor appetite or overeating	0	1	2	3
Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3

How difficult have these symptoms made it for you to do your work, take care of things at home, or get along with other people?❑ Not difficult at all ❑Somewhat difficult❑Very difficult ❑ Extremely difficult

Appendix C

Oral Health Impact Profile

HOW OFTEN have you had the problem during the last year?

	NEVER	HARDLY EVER	OCCAS-IONALLY	FAIRLY OFTEN	VERY OFTEN	DON'T KNOW
1. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
2. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
3. Have you had painful aching in your mouth?	0	1	2	3	4	5
4. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
5. Have you been self-conscious because of your teeth, mouth or dentures?	0	1	2	3	4	5
6. Have you felt tense because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
7. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
8. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
9. Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
10. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5

11. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
12. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
13. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5
14. Have you been totally unable to function because of problems with your teeth, mouth or dentures?	0	1	2	3	4	5

Appendix D

The Index of Dental Anxiety and Fear (IDAF-4C)

The following questions relate to how you feel about going to the dentist.

1. How much do you agree with the following statements?	Disagree	Agree a little	Somewhat agree	Moderately agree	Strongly agree
(a) I feel anxious shortly before going to the dentist.	1	2	3	4	5
(b) I generally avoid going to the dentist because I find the experience unpleasant	1	2	3	4	5
(c) I get nervous or edgy about upcoming dental	1	2	3	4	5
(d) I think that something really bad would happen to me if I were to visit a dentist.	1	2	3	4	5
(e) I feel afraid or fearful when visiting the dentist.	1	2	3	4	5
(f) My heart beats faster when I go to the dentist.	1	2	3	4	5
(g) I delay making appointments to go to the	1	2	3	4	5
(h) I often think about all the things that might go wrong prior to going to the dentist.	1	2	3	4	5

2. Do the following statements apply to you?	Yes	No
(a) Going to the dentist is actively avoided or else endured with intense fear or anxiety.	1	2
(b) My fear of going to the dentist has been present for at least 6 months.	1	2
(c) My fear, anxiety or avoidance of going to the dentist significantly affects my life in some way (dental pain, avoiding eating some foods, embarrassed or self-conscious about appearance of teeth or mouth, etc.).	1	2
(d) I am afraid of going to the dentist because I am concerned I may have a panic attack (abrupt fear with sweating, pounding heart, fear of dying or losing control, chest pain	1	2
(e) I am afraid of going to the dentist because I am generally highly self-conscious or concerned about being watched or judged in social situations.	1	2

3. To what extent are you anxious about the following things when you go to the dentist?	Not at all	A little	Somewhat	Moderately	Very much
(a) Painful or uncomfortable procedures................	1	2	3	4	5
(b) Feeling embarrassed or ashamed	1	2	3	4	5

(c)	Not being in control of what is happening.........	1	2	3	4	5
(d)	Feeling sick, queasy or disgusted.....................	1	2	3	4	5
(e)	Numbness caused by the anesthetic................	1	2	3	4	5
(f)	Not knowing what the dentist is going to do	1	2	3	4	5
(g)	The cost of dental treatment	1	2	3	4	5
(h)	Needles or injections	1	2	3	4	5
(i)	Gagging or choking...	1	2	3	4	5
(j)	Having an unsympathetic or unkind dentist......	1	2	3	4	5

Appendix E

Visual Analog Scale

Please place a slash (/) on the line below to indicate

your present level of **comfort**:

Very uncomfortable	Very comfortable

Please place a slash (/) on the line below to indicate

your present level of **anxiety**:

No anxiety	Worst anxiety

Appendix F

Therapy Satisfaction Scale

Please circle the number that best describes your satisfaction with the intervention.

		Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1.	I am satisfied with the quality of the intervention I received.	1	2	3	4	5
2.	My needs were met by the intervention.	1	2	3	4	5
3.	I would recommend the intervention to a friend.	1	2	3	4	5
4.	I would return to the intervention if I needed help.	1	2	3	4	5
5.	The therapy dog was friendly and warm towards me.	1	2	3	4	5
6.	I am now able to more effectively deal with my dental anxiety.	1	2	3	4	5
7.	I thought the intervention was an appropriate length.	1	2	3	4	5

8. How much did the intervention help you deal with your dental anxiety? (check one)

Made things a lot better	____
Made things somewhat better	____
Made no difference	____
Made things somewhat worse	____
Made things a lot worse	____

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