Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Do Certified Therapy Dogs Improve Behavior and Reduce Anxiety in Children Who Receive Administration of a Local Anesthetic for Dental Procedures? A Randomized Controlled Trial

NCT06057090

SUMMARY

You and your child are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to compare whether the presence of one of MUSC's certified therapy dogs improves behavior and reduces anxiety in pediatric dental patients, compared to patients who do not have a therapy dog present during treatment. If you agree to allow your child to participate, study procedures will begin at your child's next clinical treatment visit and will last no more than one hour. During this study, your child will be randomly assigned to one of two groups. This means that they have a 50/50 chance (like flipping a coin) of being in either group. Participants assigned to group A will undergo their clinical dental procedure without the presence of a certified therapy dog, while participants in Group B will get a chance to meet the therapy dog in the room before their dental procedure begins and will undergo their clinical procedure with a therapy dog present in the room.

At the treatment appointment, a member of the study team will observe your child during their procedure and assess their behavior. The study team will also record your child's heart rate and oxygen saturation, as well as the percentage of nitrous oxide they are being given. After your child's treatment but before you leave the treatment room, you will have the opportunity to answer a few short questions about your opinion of your child's participation in the study.

A potential risk to you and your child in participating is that you or your child may be fearful of the certified therapy dog or have an unknown allergy to the dog. There is a risk of a loss of confidentiality of you or your child's personal information as a result of participation in this study. There is a possibility of no direct benefit to you or your child by participating, but the information gained from the study will help the research team learn more about the use of certified therapy dogs in the pediatric dental setting. You and your child do not have to participate in this study to have your child's condition treated. The alternative would be for your child to continue with their scheduled clinical appointment without being in this study.

A. PURPOSE OF THE RESEARCH

Anxiety and behavior issues are common in pediatric dental patients and can interfere with treatment. The use of a certified therapy dog in the pediatric dental setting is an emerging and promising non-

medication option to aid in treatment. While the study of the use of pet therapy in pediatric dentistry is growing, to our knowledge there has not been a clinical trial studying the use of a certified therapy dog in the dental operatory during procedures requiring an injection.

There are two main purposes of this research: 1) to understand whether the presence of a certified therapy dog during dental procedures requiring the injection of a local anesthetic reduces anxiety and improves behavior in children and 2) to understand parents'/legal guardians' views of the use of a certified therapy dog during their child's dental procedure.

Please read this consent form carefully and take your time making your decision. As your study doctor or study team discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You and your child are being asked to participate in this study because your child will receive dental treatment that requires an injection of a local anesthetic and will have a procedure that will last one hour or less. The investigator in charge of this study at MUSC is Dr. Julie Marshall. The study is being done at 1 site (Medical University of South Carolina, Department of Pediatric Dentistry). Approximately 70 children will take part in this study; and approximately 70 parents will take part in this study.

A grant from the South Carolina Clinical & Translational Research Institute with an academic home at the Medical University of South Carolina will sponsor this study. Portions of Dr. Marshall's and Dr. Williams' and their research team's salaries will be paid by this grant.

B. PROCEDURES

If you agree to allow your child to participate, the following will happen:

1. Information will be collected from your child's dental medical record from their initial assessment visit. This information, in addition to the proposed treatment plan, is used to determine if your child is eligible to participate in the study.

2.a. Your child will be randomly assigned, like the flip of a coin, to either Group A or Group B. If your child is randomized to Group A, they will undergo their next clinical dental procedure per standard of care, which includes the administration of nitrous oxide and the injection of a local anesthetic without the presence of a therapy dog. If your child is randomly assigned to Group B, they will undergo their next clinical dental procedure (including the administration of nitrous oxide and the injection of a local anesthetic) with a therapy dog present. See more information below.

2.b. You will not know to which group your child is assigned before they arrive for their clinical treatment visit.

3. At the end of your child's procedure, parents of children in both treatment groups will be asked to complete a survey about their child's experience. The survey should take no more than 5 minutes to complete.

Group A (Control group)

If your child is assigned to Group A, the following will happen:

1. Your child will receive standard of care for their procedure at the treatment visit. Standard of care includes the administration of nitrous oxide and the injection of a local anesthetic prior to the procedure. Your child's heart rate, oxygen saturation, and the percentage of nitrous oxide will be recorded at four points during the appointment: in the chair before the scheduled dental procedure, in the chair after administration of nitrous, during the injection of local anesthetic, and in the chair after the scheduled dental procedure. In addition to these measurements, a member of the study team will also record your child's behavior during treatment on a four-point scale. This scale is called a Frankl score and is a common way to measure behavior in dental patients who are children.

2.a. When you and your child are taken to the treatment room, your child will be seated in the treatment chair, and their heart rate, oxygen saturation, and their behavior on a four-point scale will be recorded.

2.b. Your child will receive nitrous oxide, and their heart rate, oxygen saturation, the percentage of nitrous oxide, and their behavior on a four-point scale will be recorded.

2.c. Your child's providers will give an injection of a local anesthetic, and their heart rate, oxygen saturation, the percentage of nitrous oxide, and their behavior on a four-point scale will be recorded.

2.d. Once your child's provider has determined that the anesthetic has numbed the treatment area, the scheduled dental procedure will begin.

2.e. After the completion of the scheduled dental procedure, your child will still be in the treatment chair and their behavior on a four-point scale will be recorded.

3.a. Prior to your entrance into the dental operatory, an area of the floor will be sampled for its microbial concentration. This involves swabbing a section of the floor and storing it in a container.

3.b. After treatment is completed and you and your child have left the room, a section of the floor will again be sampled for its microbial concentration.

Group B (Intervention group)

If your child is assigned to Group B, the following will happen:

1. Prior to your entrance into the dental operatory, the area of the floor where the therapy dog will sit will be sampled for its microbial concentration. This involves swabbing a section of the floor and storing it in a container.

2.a. When you and your child are taken to the treatment room, one of MUSC's certified therapy dogs and its handler will already be in the room. You and your child will be introduced to the therapy dog, and then the therapy dog and its handler will move away from the dental chair to the other side of the room, where they will stay throughout the scheduled dental procedure.

2.b. Your child will be seated in the treatment chair, and their heart rate, oxygen saturation, and their behavior on a four-point scale will be recorded.

2.c. Your child will receive nitrous oxide, and their heart rate, oxygen saturation, the percentage of nitrous oxide, and their behavior on a four-point scale will be recorded.

2.d. Your child's providers will give an injection of a local anesthetic, and their heart rate, oxygen saturation, the percentage of nitrous oxide, and their behavior on a four-point scale will be recorded.

2.e. Once your child's provider has determined that the anesthetic has numbed the treatment area, the scheduled dental procedure will begin.

2.f. After the completion of the scheduled dental procedure, your child will still be in the treatment chair and their behavior on a four-point scale will be recorded.

3. After you and your child and the therapy dog and handler leave the room, it will again be sampled for its microbial concentration, to see if the presence of the dog changes the concentration.

Your child may be withdrawn from the study for the following reasons: missing their scheduled appointment, fear of the dog, allergy to the dog, behavior that jeopardizes the safety of patient/staff, negative reaction to therapy dog or dental materials, or if their medical status has changed making them no longer eligible.

If your child is removed from the study due to any of the reasons above, the procedure will continue if it is safe to do so. If the treatment must be terminated, your child will be stabilized, and the dental provider will explain options for proceeding/completing treatment.

C. DURATION

Participation in the study involves one dental treatment visit that will last no more than one hour.

D. RISKS AND DISCOMFORTS

Therapy Dog

A potential risk to you and your child in participating is that you or your child may be fearful of the certified therapy dog or have an unknown allergy to the dog.

Randomization Risk

It is also possible that your child may be randomly assigned to the group without the therapy dog in the room during the procedure, which might cause them to be upset. Another potential risk is that the group your child is randomly assigned to may be found more or less effective in helping their anxiety and behavior.

Risk of Loss of Confidentiality

There is a risk of a loss of confidentiality of your child's personal information as a result of participation in this study. Although this risk is minimal, information within your child's dental medical record will be viewed by individuals authorized to access the record. The research team will make

every effort to keep all research information confidential in the dental medical record that identifies your child to the extent allowed by law.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

If your child is a patient of the MUSC College of Dental Medicine, he/she has a MUSC dental medical record. If your child has never been a patient at MUSC, a MUSC dental medical record will be created for the purposes of this study. Results of procedures will be included in your child's MUSC dental medical record. All information within your dental medical record can be viewed by individuals authorized to access the record. The research team will make every effort to keep all research information confidential in the medical record that identifies your child to the extent allowed by law.

F. BENEFITS

The potential benefit to your child is that the group that includes the certified therapy dog may prove to be more effective in reducing anxiety than the other group, although this cannot be guaranteed. There is a possibility of no direct benefit. However, it is hoped that the information gained from the study will help the research team learn more about how the use of certified therapy dogs can be used in the pediatric dental setting to reduce fear and anxiety and improve behavior, and whether parents would support their use.

G. COSTS

There will be no additional cost to you as a result of being in this study. However, the care for your child's condition (care they would have received whether or not they were in this study) will be charged to you or your insurance company. It is possible that your insurance company will refuse to pay for dental treatment costs, in which case you will be held financially responsible. You may wish to contact your insurance company to discuss this further. Please ask Dr. Julie Marshall if you would like to know more about which tests and studies are being done solely for research purposes.

H. PAYMENT TO PARTICIPANTS

Your child will not be paid for participating in this study.

I. ALTERNATIVES

Your child does not have to participate in this study to have his/her condition treated. The alternative is to not participate in the study, though your child will still receive care.

J. DATA SHARING

Information about your child (including identifiable private information) may have all of their identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you.

K. DISCLOSURE OF RESULTS

The results of this research will not be shared with others. Information about your child (including identifiable private information) may have all of his/her identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from the subject or legally authorized representative(s).

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your child's medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your child's condition.

Your study doctor and the research team will use and disclose (release) your child's health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study who may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your or your child's identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

M. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you or your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Results of this research will be used for the purposes described in this study. This information may be published, but you or your child will not be identified. Information that is obtained concerning this research that can be identified with your child will remain confidential to the extent possible within State and Federal law. The sponsor will receive copies of the research records. The investigators associated with this study, employees of the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that your child is injured as a result of participation in this study, you should immediately take your child to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that your child is in a research study. They will call your child's study doctor who will make arrangements for your child's treatment. If the study sponsor does not pay for your child's treatment, the Medical University Hospital and the physicians who render treatment to your child will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to your child.

You and your child's participation in this study is voluntary. You or your child may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you or your child decides to do this. You or your child's decision not to take part in the study will not affect you or your child's current or future medical care or any benefits to which you or your child is entitled.

The investigators and/or the sponsor may stop you or your child's participation in this study at any time if they decide it is in you or your child's best interest. They may also do this if your child does not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my child's participation in this study or study related injury, I may contact ***Dr. Julie Marshall at 843) 792-7981***. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about my child's rights as a research subject in this study, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792- 4148. This includes any questions about my rights as a research subject in this study.

I agree for my child to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____ _____
Signature of Person Obtaining Consent Date *Printed Name of Minor Participant

_____
Signature of Adult Participant Date

_____
Signature of Participant's Personal Representative (if applicable) Date

_____
Printed Name of Personal Representative (if applicable)

Relationship: ___ Spouse ___ Parent ___Next of Kin ___Legal Guardian* ____ DPOA for Healthcare*

**(If you are the health care agent or guardian, please provide proof of your authority to act on behalf of the patient)*