

Study Title:

Assessing mechanisms of anxiety reduction in animal-assisted interventions for
adolescents with social anxiety

NCT #03249116

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TUFTS UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH STUDY

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PURPOSE AND DURATION: The purpose of this study is to investigate the specific mechanisms by which interacting with a therapy dog may reduce anxiety, providing critical information about the processes involved in effective animal-assisted interventions for mental health. The duration of the study is approximately 1.5 to 2 hours.

PROCEDURES: Eligible participants will be randomized into one of three conditions: 1) control group (no contact with a therapy dog); 2) social interaction with a therapy dog (no physical contact); and 3) social + physical interaction with a therapy dog. Participants in all three conditions will complete a public speaking task and a mental arithmetic performance challenge. During the experiment, your child be asked to wear a wristband with two attached sensors (similar to a watch or a FitBit) to measure his or her heart rate, electrodermal activity, body temperature, and movement. They will be asked to complete a self-report questionnaire of their anxiety level at baseline, during each portion of the task, and at the end of the experiment (6 times total). All sessions will be video recorded for research purposes. If you do not consent to have your child videotaped, your child will not be asked to participate in the study.

RISKS AND DISCOMFORT: The risks associated with this study are minor, and this study protocol has been used widely in many different youth populations without causing undue risk to participants. However, testing and answering questions about personal feelings and participating in the social stressor situation could be stressful for your child. Your child will be reminded that he/she may stop participating at any time during the study. There is very little risk associated with the wristband, but if minor irritation or discomfort takes place, we will remove the wristband immediately. For participants who are randomized to the conditions that involve interacting with a dog, there is always minor risk associated with interacting with live animals. However, all animals are trained therapy dogs through Tufts Paws for People and Pet Partners. The therapy dogs undergo an extensive evaluation process.

BENEFITS: There are no direct benefits to participating in this study.

CONFIDENTIALITY: Your child's name and other identifying information will be stored with his or her data, therefore there is minor risk of a breach of confidentiality. However, all data will be stored securely through a password-protected, HIPAA-compliant database protected behind the Tufts Medical Center firewall. All identifying information will be removed from the surveys and video data prior to analysis. The results of this study may be published in a scholarly book or journal, presented at professional conferences or used for teaching purposes. In addition, we will make the de-identified data we collect from your child and other participants accessible to the public via a web repository. This will enable interested parties, like other researchers, to reproduce our results. All of your child's information will be kept in strict confidence; your child will never be personally identified in any communication or publicly-accessible data set. Video of your child will only be viewed by the research team, and will not be made publicly available.

COMPENSATION: Your child will receive a \$75 gift card for participating in the study.

REQUEST FOR MORE INFORMATION: You may ask more questions about the study at any time. Please e-mail the principal investigator at megan.mueller@tufts.edu or call (508) 887-4543 with any questions or concerns about the study. In addition, you may contact Lara Sloboda at the Tufts University Office of the Institutional Review Board at (617) 627-3417.

WITHDRAWAL OF PARTICIPATION: Your child's participation is voluntary. Should you or your child decide at any time during the study that your child no longer wishes to participate, you may withdraw your permission and discontinue your child's participation without penalty or loss of benefits.

SIGNATURE: I confirm that I understand the purpose of the research and the study procedures. I understand that I may ask questions at any time and can withdraw my child from participation without prejudice. I have read this consent form. My signature below indicates my willingness to allow my child to participate in this study.

Parent/Guardian Signature

Date

Printed Name of Parent/Guardian

Researcher Signature

Date

Printed Name of Researcher

ASSENT TO PARTICIPATE IN RESEARCH STUDY

PRINCIPAL INVESTIGATOR: Megan Mueller, Ph.D.

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What is this study about? We are trying to understand how therapy dogs can help reduce stress.

What will you do in the study? First we will ask your parent or guardian for their permission for you to participate in our study. You will be assigned to one of three groups: 1) no contact with a therapy dog, 2) social contact with a therapy dog (no petting), or 3) petting a therapy dog. During the study, you will be asked to talk to the researchers as well as do some math problems. We will also ask you to wear a wristband connected to some adhesive sensors (similar to a watch or a FitBit) to measure your heart rate, body temperature, movement, and skin activity. You will also complete a short survey during each portion of the study (6 times total). We will be video recording the sessions as part of the study. If you do not consent to being videotaped, you will not be asked to participate in the study. The entire study will take approximately 1.5-2 hours.

How will my privacy be protected? To protect your privacy, we will store all of your information in a secure database at Tufts, and only the research team will have access to your name and other identifying information. Before we use your survey and video information, we will remove your name and other identifying information from the surveys. Although the results from the survey may appear in books or journals, your name will never be used. After we remove your name and any other identifiers, information we collect from you and other participants will be made available to other researchers. We will not share the video data with anyone outside of the research team.

Could anything bad happen to me? Nothing bad will happen to you if you decide you do not want to participate in this study. If you do decide to participate, there are no right or wrong answers to the questions we ask you. There may be some questions that you think are hard or that you do not know how to answer. That is okay. You do not have to answer any question that you do not want to. Also, if you start to participate in the study and decide you want to stop, you can whenever you want. Choosing to stop is perfectly fine. There is very little risk with wearing the wristband, but if it is uncomfortable for you, we will remove it immediately. In addition, if you are assigned to one of the therapy dog groups, there is always a minor risk of physical injury when interacting with animals. However, the dogs in this study are highly trained therapy animals and the risk is very low.

Do I get anything from the project? By participating in the study, you will receive a \$75 gift card.

What should I do if I have questions? If you have any questions about this study or the assessment, either you or someone at home can contact me. My phone number is (508) 887-4543 and my email address is megan.mueller@tufts.edu. Also, if you or someone at home has questions about your rights in helping out in this study, you can call Lara Sloboda at the IRB Office at (617) 627-3417 or email her at lara.sloboda@tufts.edu.

What else should I know? If you decided you want to participate in the study, please know that you can stop at any time.

SIGNATURE: I understand what this research is about and what I am asked to do if I decide I want to participate. I know that I can ask any questions that I have at any time. I also understand that I can stop participating at any time that I want. I am writing my name below after I have read information about the study and have agreed to be a participant.

Participant Signature

Date

Printed Name of Participant

Researcher Signature

Date

Printed Name of Researcher