

Preliminary Efficacy of Occupational Therapy Integrating Horses on Self-regulation in Youth with
Autism Spectrum Disorder

NCT05846932

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Parental/ Legal Guardian Permission for Minor's Participation in Research

STUDY TITLE: Preliminary efficacy of occupational therapy integrating horses on self-regulation in youth with autism spectrum disorder (ASD)

PRINCIPAL INVESTIGATOR: B. Caitlin Peters, Ph.D., OTR/L, Assistant Professor

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SPONSOR: National Institutes of Health (NIH)

This is a parental/legal guardian permission form for research participation. It contains important information about this study and what to expect if you permit your child to participate.

Your child's participation is voluntary. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether to permit your child to participate. If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form.

WHAT IF I HAVE QUESTIONS?

For questions or concerns about the study, you may contact B. Caitlin Peters (970) 491-1469.

For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact the CSU Institutional Review Board at: CSU_IRB@colostate.edu.

CONCISE STATEMENT OF STUDY

This research study aims to answer if occupational therapy integrating horses improves self-regulation in youth with ASD. You may be interested because your child is ages 6-11 and diagnosed with autism. This research study will take 9 months – 1 year. There are some risks to participating in this study, like being scared of the horse, being injured by a horse, or being injured during activities in the clinic (e.g., falling off of a swing). Your child will receive 10 free weeks of occupational therapy either in a clinic or equine setting. If your child is assigned to the clinic setting, they will receive one free adaptive horseback riding lesson after 10 weeks of occupational therapy. We hope that this research will benefit the autism community by providing more information about interventions for people with autism. You can find more details on this study following in the body of this consent form. If you are interested in continued discussion, we would like to discuss more with you through this consent presentation.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to learn if occupational therapy integrating horses improves self-regulation in youth with ASD. We are interested if the intervention makes youth feel more calm/relaxed and focused/alert.

WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?

Your child is being asked to participate in the study because they fit these criteria:

- Age 6-11 and diagnosed with ASD
- Verbally fluent with a nonverbal IQ \geq 65
- Experiences irritability (irritable mood, aggression, temper outbursts, whining, etc.)
- able to tolerate a helmet and ride a horse for 10 minutes while following safety rules
- able to provide a saliva sample by holding a foam swab in their mouth for 1-min
- able to attend all study sessions

Your child should not participate in this study if they:

- weigh more than 200 pounds
- smoke or regularly use steroids
- currently receive occupational therapy
- have 10+ hours of horseback riding experience in the past 6 months.
- Have a history of animal abuse or phobia of horses
- Have a sibling or another child in the household who has already enrolled in the study

You are being asked to participate in this study because you are a parent/legal guardian of a child with ASD who lives with the child at least 50% of the time and are able to attend all study sessions.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

If you are eligible for the study, you will be scheduled to participate in therapy in Summer 2023, Fall 2023, Spring 2024, Summer 2024, or Fall 2025. Scheduling is based on first-come-first-served availability. If you are scheduled to a therapy session more than 3-months away, you will be asked to complete an online questionnaire 3-months before therapy begins. One week before therapy begins, you'll participate in a goal-setting visit at Temple Grandin Equine Center (TGEC). Next, your child will participate in ten weekly 60-minute occupational therapy sessions at TGEC. Your child will be asked to provide 4 saliva samples each week, and you will be asked to fill out questionnaires on the first and last week. After 10 weeks of therapy you will be asked to participate in a 15-minute phone call with an occupational therapist. Six months after therapy concludes you'll be asked to complete a final questionnaire online.

What will I do?	When?	Who?	How long will it take?	Where?
3-month waitlist online questionnaires	3 months before therapy	Parent/Legal Guardian	30 minutes	Online
Goal setting visit	1 week before therapy	Parent/Legal Guardian & Child	1 hour	TGEC
Occupational therapy in either a clinic or an equine setting	Weeks 1 – 10	Child	Ten 1-hour sessions; 10 hours total	TGEC
Parent education on child's self-regulation skills	Weeks 1 – 10	Parent/Legal Guardian	10 minutes each time; 1.66 hours total	TGEC
1 Saliva sample before each therapy session	Weeks 1 – 10	Child	5 minutes each time; 50 minutes total	TGEC
1 Saliva sample during each therapy session	Weeks 1 – 10	Child	1 minute each time; 10 minutes total	TGEC
2 Saliva samples after each therapy session	Weeks 1 – 10	Child	15 minutes each time; 2.5 hours total	TGEC
Fill out questionnaires	Week 1 & Week 10	Parent/Legal Guardian	30 minutes each time; 1 hour total	TGEC
Phone call with research assistant	1 week after therapy	Parent/Legal Guardian	15 minutes	Phone
6-month follow-up online questionnaires	6 months after therapy	Parent/Legal Guardian	30 minutes	Online
Total	9 months – 1 year		20 hours	

The arena at TGEC has glass walls and therefore is visible to the public. If your child is assigned to the equine setting, the public will not be able to hear anything in the arena, but they may see you or your child during the therapy session. There will be no indication that you or your child are participating in research—the public will not be able to differentiate you or your child from any other community member receiving therapy at TGEC. If you prefer, your child can receive therapy in one-half of the arena with a curtain dropped, so that their therapy session is not visible to the public. You can indicate your preference at the bottom of this form. If you change your mind, you can indicate your request verbally to research staff anytime throughout the study period.

WHAT WILL I BE ASKED TO DO?

If you volunteer to participate in this study, you will be asked to do the following:

3-Month Waitlist Online Questionnaires

- If your child is scheduled to participate in therapy that begins more than 3 months after today's screening visit, you will be asked to complete questionnaires 3 months before therapy begins.
- These questionnaires will be sent to you via an online survey
- Questionnaires will confirm your child is still eligible for the study and will ask questions about your child's behavior.
- A consistent parent/legal guardian must complete all study questionnaires

Goal Setting Visit

- You will be asked to complete a survey prior to attending the goal setting visit that asks you questions about your child's self-regulation behaviors, and confirms your child is still eligible for the study.
- At the goal-setting visit, you, your child, and an occupational therapist will collaboratively develop goals for your child related to self-regulation.

10 Weeks of Occupational Therapy

- Your child will be asked to attend 60-minute therapy sessions once a week for 10 weeks

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- Your child will be assigned to occupational therapy **either** in a clinic environment **or** in an equine setting. Assignment to either the clinic or equine setting is based on chance, like the flip of a coin.
- Occupational therapy in either environment will include teaching your child about different emotions and how to use self-regulation “tools” to help regulate their emotions.
- Occupational therapy in a clinic may include obstacle courses, games, swings, and other activities tailored to achieve your child’s goals.
- Occupational therapy in an equine setting may include grooming the horse, riding the horse, playing games, or other activities with horses tailored to achieve your child’s goals.

Parent Education on Child’s Self-regulation Skills

- Each week before therapy, while your child is with study staff providing a saliva sample, the occupational therapist will check in with you for about 5 minutes and ask questions about your child’s self-regulation at home.
- Each week after therapy, while your child is with study staff providing a saliva sample, the occupational therapist will provide you with parent education for about 5 minutes. Education will cover the self-regulation skills your child worked on during therapy and how to help them with that self-regulation skill at home.

Saliva Samples

- Before each weekly therapy session, your child will sit at a table with a movie, legos, and art activities for 5-mins and then provide a saliva sample by holding a foam swab in their mouth for 1-min. If it’s too difficult to sit for 5 minutes, your child can go on a walk with study staff (sample 1)
- During each weekly therapy session, 10 minutes into the session your child will provide a saliva sample by holding a foam swab in their mouth for 1-min (sample 2). If your child is assigned to the equine environment this sample will be given while mounted on a horse. If your child is assigned to the clinic group this sample will be given while in the clinic.
- After each weekly therapy session, your child will sit at a table with a movie, legos, and art activities for 15 minutes. Your child will provide a saliva sample at the beginning (sample 3) and end (sample 4) of the 15 minutes by holding a foam swab in their mouth for 1-min. If it is too difficult to sit for 15 minutes, your child can go on a walk with study staff.
- We will send the saliva samples to a lab where they will measure cortisol and alpha-amylase levels, to see if therapy changes how relaxed and focused your child is.

Fill Out Questionnaires

- On Week 1 and Week 10 of therapy, you will be asked to fill out questionnaires about your child’s behavior.

Goal Progress Phone Call

- After the 10 weeks of therapy, a research assistant will call you to ask about your child’s performance on the goals set during the goal-setting visit.
- The phone call will be recorded to allow for review by the research team afterwards.

6-month Follow-up Survey

- 6 months after therapy you will be asked to complete an online survey with questions about your child’s behavior

ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY?

- Your child will receive 10 free sessions of occupational therapy either in a clinic or in an equine setting
- Occupational therapy in a clinic group only: your child will receive one free adaptive horseback riding lesson after completion of 10 weeks of occupational therapy in a clinic.
- This study may advance the knowledge of how occupational therapy impacts the daily lives of children with autism. It may benefit the autism community by providing more information about a potentially effective intervention for youth with autism.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- If your child is assigned to occupational therapy in an equine setting, there are inherent risks to interacting with horses. It is possible your child could feel sore for a couple days after riding, but the soreness usually improves after a couple of weeks. While uncommon, there are minor physical risks such as being bumped by the horse or stepped on by the horse. While very rare, it is also possible that your child could fall off of the horse or be otherwise injured by the horse, causing a major injury such as concussion, broken bone, or abdominal injury. Temple Grandin Equine Center is a PATH, Intl facility and therefore follows all best practices to ensure participant safety including trained staff and volunteers, and use of helmets and appropriate tack. If an injury occurs, basic first aid is provided on site and emergency personnel are called if needed; an incident report is also completed and the participant or parent/legal guardian are called for a follow-up call within 24 hours.
- If your child is assigned to occupational therapy in an equine setting, it is possible that being around horses may cause feelings of fear, nervousness, or discomfort. Staff at the riding center will do their best to make your child feel comfortable through slowly introducing the horse and providing encouragement. Your child will never be forced to interact with or mount a horse if s/he does not want to. While unlikely, if your child demonstrates negative

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emotions (anxiety, fear, anger) beyond what can be handled in-the-moment by the occupational therapist, s/he will be referred to outside counseling or therapy to process those emotions.

- If your child is assigned to occupational therapy in a clinic, gross motor activities may include use of swings, trampolines, or a short rock-climbing wall. While uncommon, it is possible that your child could get hurt during these gross motor activities. Occupational therapists will be trained in safe use of all equipment.
- While providing saliva samples, it is possible your child will be uncomfortable.
- We will share the results of the screening assessments with you, and it is possible the results may be difficult to hear. We will take breaks and answer questions as needed.
- While filling out surveys, you will be asked about your child's behavior. Thinking about this personal information may bring up feelings of joy, sorrow, nervousness, or other emotions. At any point during the questionnaires, you can choose not to answer a question or stop filling them out completely. There are no right or wrong answers to the questions.

WHAT HAPPENS IF MY CHILD IS INJURED?

If you believe you or your child have been injured because of participation in this study, please contact the Principal Investigator at the number listed in the "What if I Have Questions" section of this form. The Colorado Governmental Immunity Act determines and may limit Colorado State University's legal responsibility if an injury happens because of this study. Should you need medical assistance, you or your health insurance will be responsible for the costs.

WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY?

If you complete a 3-month waitlist questionnaire online, you will receive a \$15 Amazon gift card. For completing Week 10 and 6-month follow-up questionnaires, you will receive \$15 Amazon gift cards each time.

What will I do?	Compensation
Complete 3-Month Waitlist Questionnaires Online	\$15
Complete Week 10 Questionnaires	\$15
Complete 6-Month Follow-up Questionnaires Online	\$15
TOTAL	Up to \$45

ARE THERE ANY COSTS TO PARTICIPATE IN THIS STUDY?

You are responsible for travel costs (gas, transit) to and from TGEC.

WHO WILL SEE THE INFORMATION THAT I GIVE?

All information gathered in this study will be kept as confidential as possible. Your privacy is very important to us and the researchers will take every measure to protect it. Your information may be given out if required by law; however, the researchers will do their best to make sure that any information that is released will not identify you. No reference will be made in written or oral materials that could link you to this study. For this study, we will assign a code to your data so that the only place your name will appear in our records is on the consent, the hard-copy questionnaires, in our secure online REDCap database, and in our data spreadsheet which links you to your code. Only the research team will have access to the link between you, your code, and your data. Data will be stored in a secure online REDCap database, a restricted access folder, and a locked drawer in a restricted-access office at CSU for at least three years after completion of the study. If you or your child are not eligible for the study or withdraw from the study, we will keep all information we have already collected with the study data as a record of your participation, but no new data will be collected.

There are organizations that may inspect research records that may include yours. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor
- *For funded studies, the CSU financial management team may request an audit of research expenditure, in which only your participating in the research may be shared, but not your research data.*
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- Department of Health and Human Services

Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits.

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National Institutes of Health (NIH) has additional protections for research they fund. Namely, they consider your data to be protected under a "Certificate of Confidentiality." This Certificate gives added protection for your privacy even if the records are subpoenaed. We will not give information to anyone unless you provide a signed release telling us to do so, or unless we have reason to suspect: 1) abuse, neglect, or endangerment of a child or elder; 2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these situations, we may have to make a report to the appropriate authorities.

If the U. S. Department of Health and Human Services (DHHS) audits our research project, they can have access to information about you. However, they cannot report it to the police or use it for any reason besides the audit. Even though a Confidentiality Certificate was issued, it does not mean that the Secretary of DHHS supports this research.

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

The research team works to ensure confidentiality to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. However, your participation in this online survey involves risks similar to a person's everyday use of the internet.

If you choose to take part in this study, your private information will be collected. Any identifiers linking you to your private information will be removed. After we remove those identifiers, the information could be used for future studies or distributed to another research for future research studies without your permission.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court OR *to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else.*

HIPAA AUTHORIZATION

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The Principal Investigator must obtain your authorization (permission) to use or release any health information that might identify your child.

What information may be used and shared?

The Principal Investigator and study staff will use and share your child's health information as part of this research study. This may include your child's name, address, or other facts that could identify the health information as your child's. Examples of the information that may be used are:

- Information created or collected during the research. This could include your child's autism diagnosis, therapy progress notes, and dates or results from any assessments, such as the ADOS-2 or Leiter-3.

Who will receive information about you?

The study staff may share your child's personal health information with:

- the funding agency, including persons or companies working for or with the funding agency
- Colorado State Institutional Review Board
- Department of Health and Human Services (DHHS) agencies
- Other regulatory agencies responsible for oversight of the conduct of the research
- The occupational therapists providing services in the study

Why will this information be used and/or given to others?

The Principal Investigator, Research Study team, funding agency, and the groups listed in the section above may use your health information:

- to complete this research
- to evaluate the results of the study
- to check that the study is being done properly

Is my health information protected after it has been given to others?

Your child's health information may be further shared by the groups above. If shared by them, the information may no longer be covered by this Authorization and may be released without your permission.

What if I decide not to allow the use of my health information?

You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

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May I withdraw or revoke (cancel) my permission?

YES. You may withdraw your permission to use and disclose your child's health information at any time. You can do this by sending written notice to the Principal Investigator. If you withdraw your permission, you will not be able to continue being in the research study.

What happens if I want to withdraw my authorization?

Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Will my authorization expire?

This Authorization does not expire unless you withdraw it in writing.

May I review or copy the information obtained or created about me?

YES. You have the right to review and copy your child's health information. However, your access to this information may be delayed until the study is complete.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

DO I HAVE TO TAKE PART IN THE STUDY?

You or your child may leave the study at any time. If you or your child decides to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with Colorado State University.

Participant Consent:

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

The researchers would like to audio record the goal progress phone calls that occur after the 10-weeks of therapy is complete. An additional rater will listen to the phone calls to ensure reliable goal attainment ratings. Only our research team will have access to the audio recordings.

Yes, I agree to allow my phone call with a research assistant to be audio recorded _____ (initials)

No, do not audio record my phone call _____ (initials)

If assigned to the equine group, you have the choice for your child to receive therapy in the entire arena, which is visible to the public through glass walls/windows, or to receive therapy in a smaller portion of the arena curtained off from public view. Please indicate your selection below

I request my child receive therapy in the full arena, I acknowledge it is visible to the public _____ (initials)

I request my child receive therapy in a smaller portion of the arena that is curtained-off so it is not visible to the public _____ (initials)

Signature of participant

Date

Name of participant

Signature of person providing information

Date

Name of person providing information

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