COMIRB
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Principal Investigator: Robin Gabriels, Psy.D.
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Study Title: Physiological mechanisms of action relating to immediate and long-term therapeutic horseback riding intervention effects in a psychiatric population of youth with autism spectrum disorder

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You (you/your child) are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether to take part.

Why is this study being done?

This study plans to learn more about how therapeutic horseback riding (THR) works to help kids with autism spectrum disorder (ASD) to feel calm, relaxed, and/or focused/alert. We will do this by looking at how THR affects three things:

1. Electrodermal activity (EDA; sweat) using the Shimmer3 EDA skin conductance device worn on the wrist area
2. Heart Rate and Heart Rate Variability (HR/HRV) using the Shimmer3 ECG cardiac monitor attached to the collarbone, chest and rib areas.
3. Salivary cortisol using a SalivaBio Children's Swab (SCS)

This study is also being done to see if benefits from therapeutic horseback riding last 6 months after riding. Finally, this study is being done to see if just learning about horses and horse care has any benefits.

You are being asked to be in this research study because your child has ASD along with other psychiatric diagnoses.

Other people in this study

Up to *170* people ages 6 – 16 years from Colorado will participate in the study.

Up to *250* people ages 6 – 16 years from both study sites combined (Colorado and Maine).

What happens if I join this study?

If you join the study, participation includes the following steps:

Step 1: One screening visit at Children's Hospital Colorado (CHCO) to meet with study staff to learn more about the study and to ensure study inclusion criterion are met. This

visit also involves completing forms (CCIF, SCQ, CASI-5) and two tests (Leiter-3 & ADOS-2). **(See Measures Table I below)**

Note 1: if your child meets study step 1 screening requirements, then they will be randomly assigned to one of three group lessons. *We will use a method of chance. This method is like flipping a coin or rolling dice. Each group will get slightly different care.*

a. Therapeutic Horseback Riding (THR) --10-weekly small group THR lessons at the Hearts & Horses riding center, Loveland, CO
b. Barn Activity (BA) --10-weekly small group BA lessons at the Hearts & Horses riding center, Loveland, CO

Note 2:
Re-screening- If after your child has been consented and randomized to a group you choose to wait 6 months or longer to begin the intervention phase, then your child will be re-screened with the ABC-irritability scale to ensure they still meet study screening requirements before they begin the intervention.

Step 2: Complete the **riding center's information form** and give your child's doctor the ***riding center's medical clearance form*** to complete and return to the riding center. **This step must be completed before moving on to step 3.**

Step 3. One riding center screening visit before your child can begin one of the small group (up to 4 participants) lessons at the riding center, Hearts & Horses in Loveland, CO. During this visit, THR and BA participants will complete a one-hour individual screening with a THR instructor to understand the child's needs and abilities, review riding center safety rules, and practice wearing the physiologic data collection devices at the riding center. Caregivers will complete one survey. The activities of this screening will include the following:

i. THR group: Sit at an art table and engage in an art or puzzle activity about horses, enter the arena, engage in a brief horseback riding activity and then dismount.
ii. BA group: Sit at art table and engage in an art or puzzle activity about horses.

Step 4. One **speech testing visit** at CHCO before starting either the 10-weeks of THR or BA. The speech assessment will be audiotaped and transcribed to allow scoring of this measure.

Step 5. 10-weekly group lessons at Hearts and Horses riding center, Loveland, CO that will each last 1 ½ hours. *Note: Those randomized to the waitlist group will not attend lessons at the riding center for their first 10 weeks in the study.* The 10-weekly lessons will involve the following:

a. All group (THR or BA) lessons will involve the following:

i. Occur between 1:00-5:00 PM in order to collect salivary cortisol when these levels typically decline.

ii. Consist of 2-4 participants, be led by a THR instructor, have at least one volunteer assigned to assist participants as needed, follow a consistent routine, and learn horsemanship skills via activities tailored to ASD learning styles outlined in the study manuals (THR or Barn).

iii. Each week of the lesson, a consistent caregiver for each participant will complete the Aberrant Behavior Checklist to rate their child's behaviors over the past week prior to the current lesson.

iv. Two of every 10-week lessons will be videotaped so that we can evaluate if the lessons are being done in a consistent manner.

v. A consistent Caregiver for each participant in the THR and BA groups will complete the Aberrant Behavior Checklist, Social responsiveness scale, Emotion Dysregulation Inventory, Quality of Life questionnaire and Crisis Mental Health Care Usage survey at weeks 1 and 10 of the lessons or wait period. *Note:* ***If you decide to postpone your child's 10-week intervention after they have already completed baseline intervention assessments (Visit III)*** *and your child has completed only up to two intervention lessons, you will be asked to complete an additional baseline assessment (caregiver forms only). The initial completed baseline assessments will not be used for data analyses. Additionally, when you child is ready to complete their 10-week intervention, they will not attend the one or two lessons they may have previously attended so that they will only complete up to 10 intervention lessons as part of their participation in the study.*

vi. **THR and BA** group participants will wear the Shimmer3 skin conductance watch and Shimmer3 heart-rate monitors throughout their lessons and will provide a saliva sample right before and 20 minutes after each lesson. Caregivers will complete the sample collection log sheet each week.

b. THR group lessons-- Each participant will have an assigned horse and volunteer(s) (one horse leader and up to two side walkers). Every effort will be made to allow each participant to ride a consistent horse throughout the study.

c. BA group lessons-- Each participant will have one assigned volunteer and will have no contact with horses at the riding center, just view horses at a distance. There will be a life-sized stuffed horse in the group for hands-on learning related to the weekly topic.

Step 6: One **speech testing visit** at CHCO after the 10-weeks of THR or BA group lessons.

Step 7: For THR and BA group participants only-- One 6-month follow-up testing visit that will involve a speech test for the child and caregivers completing the Aberrant Behavior Checklist, Social responsiveness scale, Emotion Dysregulation Inventory, Quality of Life questionnaire and Crisis Mental Health Care Usage survey.

Note: If you join the study, you will be a study participant for up to 11 months.

Measures Table I

Domain	Measure	Time	Study entry	Pre 10-week lessons	Each lesson	Post 10-week lessons	6 mos. Post
Cognitive	Test Child: Leiter-3 (Brief IQ)	45 min	X				
Diagnosis	Test Child: Autism Diagnostic Observation Schedule (ADOS-2)	55 min	X				
Diagnosis	Form: Social Communication Questionnaire (SCQ)	<15 min	X				
Psychiatric Symptoms	Form: Child Symptom Inventory 5 (CASI-5)	20 min	X				
Demographic	Form: Child & Caregiver Information Form (CCIF)	<15 min	X				
Emotion Regulation	Form: Emotion Dysregulation Inventory (EDI)	15-20 min		X		X	X
Social Skills	Form: Social Responsiveness Sale (SRS)	<15 min		X		X	X
Caregiver's Quality of Life	Form: The World Health Organization's Quality of Life Questionnaire Instrument	10-20 min		X		X	X
Aberrant behaviors	Form: Aberrant Behavior Checklist-Community (ABC-C)	<15 min	X	X	X	X	X
Crisis Mental Health Care Usage	Form: Crisis Mental Health Care Usage survey	5 min		X		X	X

Word Fluency	Test Child: Systematic Analysis of Language transcripts (SALT)	5 min		X		X	X
Salivary cortisol	Child's saliva sample collected via foam rod swabs	1 min			X		
Electrodermal activity	Shimmer3 EDA skin conductance device	1 ½ hr			X		
Heart rate/ heart rate variability	Shimmer3 ECG heart rate device	1 ½ hr			X		

What are the possible discomforts or risks?

Discomforts you may experience while in this study include the following:

1. This study requires some forms to be filled out by a consistent caregiver throughout the study and several tests with your child. Any results from these assessments of your child may be uncomfortable for you to hear. The study team will take breaks when possible, if needed, and will discuss results with you if you have any questions.

2. Therapeutic horseback riding is a common intervention activity that has inherent risks, which include a fall from the horse, loss of consciousness, bodily injury, dismemberment, or death. However, instructors and the individuals who walk alongside each horse and rider are specially trained and this rarely happens in THR.

3. This study involves using foam rods to collect saliva samples from your child over the course of your participation. Discomforts you may experience while in this study include an inconvenience due to having to collect these samples.

4. There is a risk that the study wristband and heart monitor devices may be uncomfortable for your child to wear while they are engaged in their therapeutic riding lesson.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

If you become pregnant, the treatment or procedures involved in the study may involve risks to the embryo or fetus, which are currently unclear.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about the benefits of THR in treating individuals with ASD and co-occurring psychiatric diagnoses.

This study is not designed to treat any illness or to improve your health. Also, there are risks as mentioned in the Discomforts and Risk Section.

There may be some benefit to you and your child which could include the following:

- If your child is in the BA group, they will receive 1 free THR lesson following their post speech assessment.
- Your child will receive some form of 10-week intervention.
- If you ask for it, you can receive a summary of the study findings that will be submitted for publication.

Are there alternative treatments?

Therapeutic horseback riding is a common and optional alternative treatment activity to more well-researched interventions for the autism population that include applied behavior analysis, cognitive behavior therapy and psychiatric medications.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being supported by the National Institutes of Health.

Will I be paid for being in the study?

You will be paid for your participation in the study.

- You will receive $20.00 for each Pre- and Post-intervention (BA or THR) speech testing visit.
- Subjects in the THR and BA groups only will receive $30.00 for completing the 6-month post-intervention testing visit.
- Monetary support for gas costs to the riding center for intervention weeks 1-10 may be available to participants, but eligibility will be determined by study personnel
- If you leave the study early, or if we must take you out of the study, you will be paid only for the visits you have completed.
    - It is important to know that payments for participation in a study is taxable income.

All participants will receive free THR or BA group lessons at the Hearts and Horses therapeutic riding center in Loveland.

The BA group will receive a free riding lesson after completing the post-lesson speech testing.

It will not cost you anything to be in the study. All group lessons/activities and testing will be paid for by this study.

It is important to know that payments for participation in a study is taxable income.

Will I have to pay for anything?

Other than mileage/gas costs driving to the therapeutic riding center, it will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

- Participants who do not meet riding center screening criteria will be removed from the study.
- Participants in the THR or BA groups who cannot tolerate wearing the biosensors will be withdrawn from the study
- Miss more than two out of the 10-week THR or BA lessons will be withdrawn from the study.
- Participants who develop significant allergic reactions to conditions at the riding center will, at the discretion of the caregiver or the study staff, be dropped from the study.
- The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, we will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Robin Gabriels, Psy.D. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Gabriels at (720) 777-3114.

You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Gabriels with questions. You can also call the Colorado Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

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

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- Children's Hospital Colorado (CHCO)

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Robin Gabriels, Psy.D.
Principal Investigator
13123 E. 16th Ave, 130
Aurora CO 80045
720-777-3114

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* **of the following health information about you collected in this study available to** the following this study's team collaborators:

- Matthew Siegel, M.D., Co-investigator, Boston Children's Hospital
- Cory Smith , Ph.D., Biosensor expert at Baylor University, Waco, TX
- Douglas Granger, Ph.D., Salivary cortisol expert at Salimetrics LLC, Carlsbad, CA
- Carla Mazefsky, Ph.D., emotion regulation consultant at University of Pittsburgh
- Laurie Burnside, Fidelity Rater for Barn Group Intervention, University of Colorado consultant
- Tamara Merritt, Fidelity Rater for THR Group Intervention and Hearts and Horses Program Director
- Alexandra Hanson, Speech Therapist, Children's Hospital Colorado and University of Colorado Consultant

Information about you that will be collected, used and disclosed and may be seen in this study:

- Name and Demographic Information (age, sex, ethnicity, etc.)
- Research Visit and Research Test records
- Physiologic data (electrodermal activity, heart rate, heart rate variability, salivary cortisol)
- Video recording of participant engaging in group lessons
- Audio recording of speech assessments to be transcribed to allow scoring of this measure.

What happens to Data, Tissue, Blood and Specimens that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data, tissue, blood, or other specimens (salivary cortisol) given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data, tissue, blood, or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

What will happen to my recorded information?
In this study we will be recording two group lessons (THR and BA) during the 10-week intervention period in order to ensure that the group lessons are delivered in a consistent manner. We will also be audio recording your child during the pre, post, and 6-month speech assessments. We will use video cameras and recordings will be stored in a secure research database server at CHCO/University of Colorado Anschutz Medical Center.
We will keep this information secure and private. Video cameras and cards will be stored in a locked cabinet in a locked room. We will destroy all video recordings at study conclusion.

Some things we cannot keep private.
We respect your right to privacy. But there are some things we cannot keep private. If you give us information about child neglect or child abuse, we have to report that to Social Services. If you give us information about hurting someone else, we have to report that to the police. If a court orders us to hand over your study records, we have to hand them over to the court.

Agreement to be in this study and use my data
I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

(Note: For children 0-7, the parents are consented using this form)

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____

----------Use the following only if applicable----------

Signature Line Below for studies including children ages 13-17 who can read this form.
Note: children 7-12 should sign a SEPARATE Assent Form.

Signature: _____ Date:_____
(Child Subject 13-17 years old; ***In addition*** to Parent Signature)

Print Name:_____