

**Multi-site study of TR  
Physiological  
Mechanisms of action  
in youth with  
co-occurring ASD &  
mental health  
diagnoses**

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ASD Study: Fidelity Coordinator

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**MARS petcare**  
A Better World for Pets

**WALTHAM**

**HEARTS & HORSES**  
Therapeutic Riding Center

**NIH** Eunice Kennedy Shriver National Institute of Child Health and Human Development

**NIH** National Institute of Nursing Research

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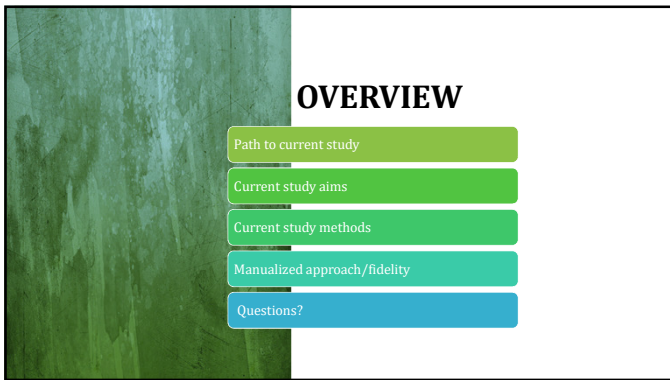
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**OVERVIEW**

- Path to current study
- Current study aims
- Current study methods
- Manualized approach/fidelity
- Questions?

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**How does Therapeutic Riding help Youth with Autism?**

<https://youtu.be/uz7bEXvMjSU>

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**2008 Pilot Study Aims**  
Evaluate effects of 10-weekly THR lessons (vs. waitlist control) on 3 core areas:

**Self-Regulation**  
ABC-C  
Irritability  
Lethargy  
Stereotypy  
Hyperactivity  
Inappropriate speech



**Adaptive Skills**  
VABS-2<sup>nd</sup> Ed  
Communication  
Daily Living  
Social

**Motor Skills**  
BOT-III  
Physical coordination  
Stability  
SIPT  
Motor planning/praxis

Gabriels, R. L., Agnew, J.A., Holt, K.D., Shoffner, A., Zhaoxing, P., Rizzano, S., Clayton, G.H., and Mesibov, G. (2011). Pilot study measuring the effects of therapeutic horserback riding on school-age children and adolescents with autism spectrum disorder. *Research in Autism Spectrum Disorders*.

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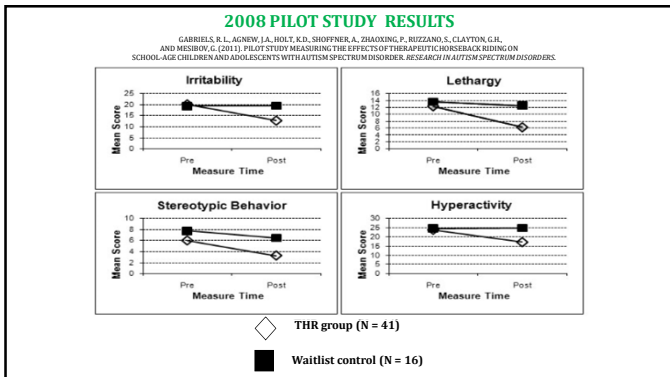
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**2008 PILOT STUDY CONCLUSIONS**

Gabriels, R. L., Agnew, J.A., Holt, K.D., Shoffner, A., Zhaoxing, P., Ruzzano, S., Clayton, G.H., and Mesibov, G. (2011). Pilot study measuring the effects of therapeutic horseback riding on school-age children and adolescents with autism spectrum disorder. *Research In Autism Spectrum Disorders*.

<u>Strengths</u>	<u>Limitations</u>
<ul style="list-style-type: none"> <li>&gt; Protocol to confirm ASD dx</li> <li>&gt; Comparison control condition (waitlist)</li> </ul>	<ul style="list-style-type: none"> <li>&gt; No <i>mature</i> manual-based treatment</li> <li>&gt; No treatment fidelity monitoring</li> <li>&gt; Unblinded outcomes evaluators</li> <li>&gt; No random assignment to conditions (THR vs Waitlist)</li> </ul>

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Study Site:  
Colorado Therapeutic Riding Center

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Notice of Award      Issue Date: 06/13/2012



RESEARCH  
Department of Health and Human Services  
National Institutes of Health  
NATIONAL INSTITUTE OF NURSING RESEARCH



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Grant Number: 5R01NR012736-03  
Principal Investigator(s):  
ROBIN L GABRIELS, PSYD  
Project Title: Effects of Therapeutic Horseback Riding on Children and Adolescents with Autism

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NIH/NINR STUDY AIMS  
NR012736-01



**AIM I: Evaluate if horse is important for change:**

10-weeks of THR vs. an active control group intervention with ASD children/adolescents (ages 6-16 yrs.) and measure:

- a. Self-regulation
- b. Communication
- c. Socialization
- d. Motor functioning

**AIM II: Determine if improvements persist for 6 months**

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## STUDY DESIGN



1. **Random assignment** stratified by NVIQ ( $\leq 85$  or  $> 85$ )
  - a) 10-week THR intervention
  - b) 10-week Barn activity (treatment-based control group)
2. **Standard THR and Barn control intervention curriculum**  
(Shoffner & Gabriels, 2008)
3. **Fidelity rating of 20% THR interventions**
4. **Evaluators (sptx/OT) blind to group assignment**
5. **Long-term follow-up** (6 mos. post intervention)
6. **Path Intl. Premiere (30 years) THR intervention site**

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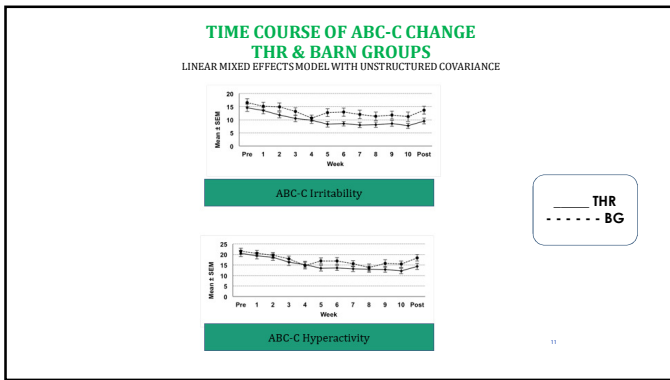
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*Journal of the American Academy of*  
**CHILD & ADOLESCENT  
PSYCHIATRY**

Volume 61 Number 7 July 2012



## 10-WEEK INTERVENTION OUTCOME RESULTS

➤ After adjusting for age, IQ and gender in the ITT analysis, **significantly greater improvements in THR group:**

- **Irritability** (ES=0.51, p=0.02) & **Hyperactivity behaviors** (ES=0.53, p=0.02) (significantly greater improvements by wk 5)
- **Social Communication behaviors** (ES=0.72, p=0.002)
- **Number of words spoken and number of new words** (ES=0.52, p=0.02)
- **Marginally significant improvement in Social Cognition Behaviors** (ES=0.32, p=0.06)

Gabriels, RL, Pan, Z, Dachant, B, Agnew, JA, Britn, N, Meshkov.  
**Randomized Controlled Trial of Therapeutic Horseback Riding in Children and Adolescents with Autism Spectrum Disorder.**  
*Journal of American Academy of Child and Adolescent Psychiatry.*  
2015; (71):543-549. PMID:4175276.

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**EXPLORATORY FINDINGS**

**THR subgroup with co-occurring psychiatric disorders:** Stronger positive outcomes (vs. BA control).

***Conclusions:** ASD psychiatric subpopulation may benefit most from THR/ higher likelihood of showing significant THR effects, a prerequisite for mediation analysis.*

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**6-month follow-up**  
Gabriels, Pan, Guerin, Dechant, Mesibov, 2018

- THR group (n = 36) sustained (marginal) improvements vs. BA Control (n = 28) in **ABC-C irritability behaviors**
- THR group (n = 36) sustained improvements in:
  - **Social communication**
  - **Number of words and new words used**

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**Replication Pilot Spring 2015**

THR n = 8; BA n = 8

Aims:

1. Replicate previous RCT findings @ new riding center
2. Trial objective measure: Salivary cortisol- stress hormone




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### REPLICATION PILOT CONCLUSIONS

Pan et al., 2018

- **Partially replicated effects** observed in the prior THR RCT.
  - Significant improvements: Hyperactivity and social cognition
  - Marginally significant improvements: Irritability and social communication behaviors.
- **Feasible to collect saliva** from children with ASD at the riding center.
- **Not sufficient statistical power to evaluate THR effects on salivary cortisol**

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### What is influencing positive observed changes?



**Mediator:**  
Emotion-related psychophysiological changes?



**Hypothesized Effect**  
THR creates a calm/focused state of arousal  
1. Sensory-related relaxation  
2. Teamwork-joint attention

**Outcome Improvements:**  
1. Decrease irritability/Hyperactivity  
2. Increase Social  
3. Increase word usage

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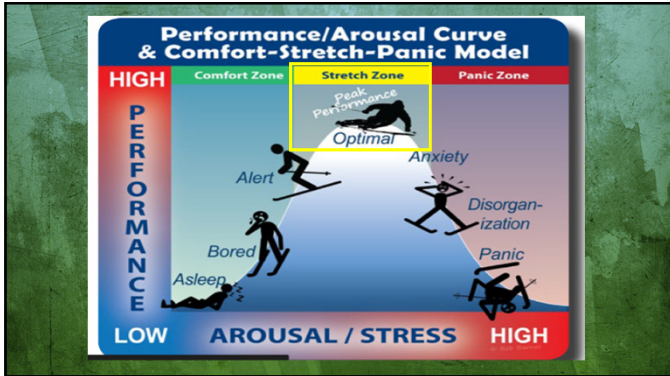
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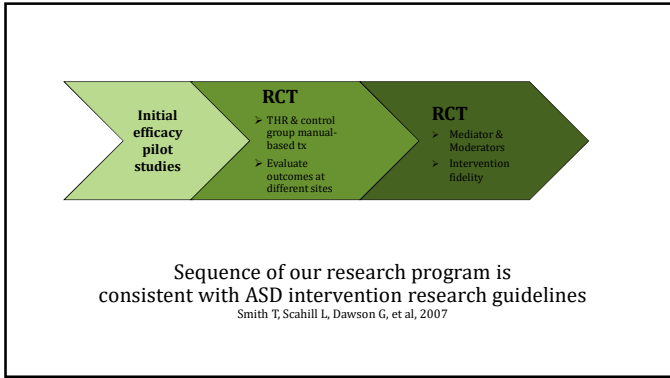
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**Current Study**

RESEARCH  
Department of Health and Human Services  
National Institutes of Health

Notice of Award  
Federal Award Date: 01/09/2020

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 1R01HD097693-01A1  
FAIN: R01HD097693

Principal Investigator(s):  
ROBIN L GABRIELS, PSYD

Project 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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**Study AIMS**

**Therapeutic Horseback Riding (THR) group**




**HEARTS & HORSES**  
Therapeutic Riding Center

**Riding To The Top**  
Therapeutic Riding Center

- **AIM 1** Identify physiological mediators of 10-week THR vs. BA control on multivariate outcomes.
- **AIM 2** Evaluate the 6-month durability of Aim 1 outcomes
- **AIM 3** Explore BA group effects & dosing effects
  - 10-week Wait-list control vs BA group
  - 10-week Hybrid group vs THR

**Barn Activity (BA) group**




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# Current Study Methods

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**Participant Inclusion Criteria**

Inclusion		Exclusion	
<b>Ages</b>	6 – 16.11 yrs	<b>Medical/Behavior</b>	Issues that prevent participation
<b>NVIQ</b>	≥40	<b>Significant riding experience</b>	Judged by riding center screening
<b>ABC-C Irritability score</b>	≥ 8	<b>Exceeding riding center's weight limit policy</b>	Specific to riding center
<b>Diagnoses</b>	ASD & Psychiatric (Mood, Anxiety, ADHD)	<b>Caregiver status</b>	Ward of the state
<b># children per family</b>	1		

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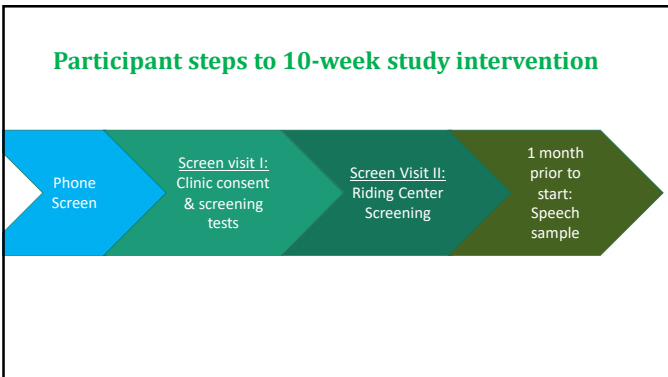
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### Participant steps after 10-week study intervention



\*We ask that participants do not have interactions with horses until their 6-month post-intervention visit

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### Collection numbers as of Spring 2023

Recruitment goals: THR = 56, BA = 56, Wait/Hybrid = 21

Therapeutic  
Horseback Riding  
N = 52

Barn Activity  
N = 34

Waitlist N = 25  
Hybrid Activity N = 15

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### Population demographics as of January 2023

\*data includes all consented individuals

N = 163

AGE	Biological Sex	ADOS Severity	IQ 540 were only included in intervention	ABC-Irritability
10	Male: 64% Female: 36%	8 (high)	96 (34-139)	13 (≤8 required for medication trials)

White/Caucasian	Black or African American	Asian/Pacific	Native American or Alaska Native	Native Hawaiian or Other Pacific Islander	Multiracial	Unknown/Not Reported
124	5	3	0	0	13	18

Hispanic or Latino	Unknown/Not Reported
21	1

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### Autonomic Bio Signals of Arousal/Stress: Wearable Physiological Sensors

**Electrodermal Activity (EDA)  
(Skin surface temperature)**

- Sympathetic autonomic nervous system arousal response (reactivity and recovery) mediates:
  - > Attention
  - > Information processing
  - > Emotion
- Low EDA = Calm state

**Heart Rate/Heart Rate Variability (HR/HRV)**

- Parasympathetic autonomic nervous system regulation of organs and body system response to arousal (e.g., slow HR to conserve NRG)
- Low HR = Calm state
- High HRV = cardio fitness & relaxation



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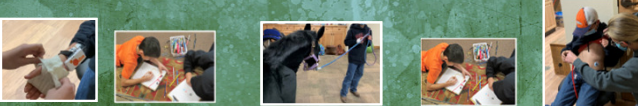
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### BA Group Daily Flow: Time Breakdown



- Arrive 20 minutes early: PUT ON EQUIPMENT
- 5 minutes: ART/quiet time
- 45 minutes: Themed Skill Activity
- 15 minutes: Wrap up and Scrapbook
- 5 minutes: ART/quiet time
- 5 minutes: TAKE OFF EQUIPMENT

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### THR Group Daily Flow: Time Breakdown



- Arrive 20 minutes early: PUT ON EQUIPMENT
- 5 minutes: ART
- 45 minutes: RIDE
- 15 minutes: GROOM
- 5 minutes: ART
- 5 minutes: TAKE OFF EQUIPMENT

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### Hormonal Bio Signals of Arousal/Stress: Salivary Cortisol

- Cortisol (stress hormone) produced by Hypothalamic Pituitary Adrenal (HPA) axis.
- Typically, HPA has a circadian rhythm:
  - High levels in AM
  - Falling levels during day
  - Lowest level (less stress) during normal sleep
- Lower cortisol levels = less stress




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### Setting the Stage for Success




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### Manualized Approach

- Riding to the Top in Portland, Maine
- Hearts & Horses in Loveland, Colorado




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# Fidelity

*What?* Fidelity asks the questions – Did you conduct your research as planned? Was it delivered to align with the protocol?

*Why?* Research needs to be **VALID** and **RELIABLE**. Validity tells us that your results measured what you wanted to measure. Reliability means your results can be consistently reproduced.

*How?* Two times per 10 - week session the following items were rated in THR and BA classes at the CO and Maine sites

- TEACHING TECHNIQUES & CLASS STRUCTURE
- VOLUNTEERS
- ENVIRONMENT




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## THR and BA Intervention Consistency Across Research Sites (CO & ME)

Consistent intervention elements	Elements that can vary
<b>Timing:</b> 45-minute Learning activities & 15-minute Wrap-up activities	Mounted time may vary by a few minutes
<b>Content:</b> 10-week themes per manuals	Teaching activities can vary by instructor preference and group learning needs
<b>Routine/Structure:</b> 45-minutes • <i>Beginning:</i> Skill review & introduce new topic/theme • <i>Middle:</i> Teaching activities to topic/theme • <i>15-minute closing routine:</i> Review skills, put away equipment, good-byes to volunteers.	45-minutes: • Activities can vary  15-minutes: • Order of wrap-up activities may vary
<b>Fidelity elements:</b> • Teaching techniques for ASD population • Volunteer involvement • Environment	• Visual cuing & behavior management methods may vary based on individual's needs/issues • Assigned volunteer and prompting level may change • Site-specific environment differences




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### THR Class Schedule

	Greet
	Put on Equipment
	Art Activity & Cortisol Sample
	Mount
	Lesson on Whiteboard
	Warm up
	Activity
	Trotting
	Cool Down
	Dismount
	Art Activity & Cortisol Sample
	Take off Equipment
	Goodbye & Thank You

Daily Schedules

### Barn Group Schedule

	Hello & Welcome
	Put on Equipment
	Choose Fidget
	Art Activity & Cortisol Sample
	Introduction & Sharing
	Skill Activity
	Scrapbook
	Wrap Up & Sharing
	Art Activity & Cortisol Sample
	Take off Equipment
	Goodbye & Thank You

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### THR and BA modules follow the same themes

~ Examples of Module Similarities ~

Skill Modules	Themes
1	Getting to know one another: Orientation & horse safety
2	Many parts make a whole: Safety & what to wear
3	Listening to our horse: Anatomy
4	Talking with our bodies: Horse emotions & body language
5	Partnering with our horse: Grooming & arena etiquette
6	Independence: Tack & Equipment
7	Together we are strong: Colors & markings
8	Be yourself: What makes you & your horse unique?
9	Adding it all up: Measurement
10	Celebrating our Accomplishments

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### BA Group: Week 3 - Anatomy of a Horse




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### THR Group: Week 3 - Listening to our Horse & Anatomy



#### Comparative Anatomy

Stretching to reach the different parts of the horse.




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### Future Directions

1. Understand why the presence and interaction with animals has beneficial effects to guide providers
2. Move field beyond "does it work" to more nuanced questions:
  - **How** it works
  - **For whom** does it work
  - **For how long** does it work
  - **Under what conditions** does it work
3. Guide future researchers to further explore mechanisms by which THR is beneficial, expanding to other populations

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# Questions?



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