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

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OVERVIEW

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

How does Therapeutic Riding help Youth with Autism?
https://youtu.be/e27bEXyMg8U
2008 Pilot Study Aims
Evaluate effects of 10-weekly THR lessons (vs. waitlist control) on 3 core areas:

- Self-Regulation
  - ANS-C
  - Irritability
  - Stereotypy
  - Impulsivity

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

- Adaptive Skills
  - VABS-2nd Ed
  - Communication
  - Daily Living
  - Social

2008 PILOT STUDY CONCLUSIONS


Strengths
- Protocol to confirm ASD dx
- Comparison control condition (waitlist)

Limitations
- No mature manual-based treatment
- No treatment fidelity monitoring
- Unblinded outcomes evaluators
- No random assignment to conditions (THR vs Waitlist)

Study Site: Colorado Therapeutic Riding Center

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
STUDY DESIGN

1. Random assignment stratified by NVIQ (<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

TIME COURSE OF ABC-C CHANGE

THR & BARN GROUPS
LINEAR MIXED EFFECTS MODEL WITH UNSTRUCTURED COVARIANCE

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=0.52, p=0.06)

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.

6-month follow-up

- 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

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
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

What is influencing positive observed changes?

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

Mediator:
Emotion-related physiological changes?

Outcome Improvements:
1. Decrease irritability/hyperactivity
2. Increase social
3. Increase word usage

Performance/Arousal Curve & Comfort-Stretch-Panic Model

- High Performance
- Low Arousal/Stress
- Comfort, Stretch, Panic Zones
- Optimal, Alert, Bored, Asleep, Panic
- Levels: Low, High
Sequence of our research program is consistent with ASD intervention research guidelines


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**Current Study**

- Initial efficacy pilot studies
- RCT
  - THR & control group randomized
  - Evaluate outcomes at different sites
- RCT
  - Mediator & Moderators
  - Intervention fidelity

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**Study AIMS**

**Therapeutic Horseback Riding (THR) group**

- **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 Wash-out control vs BA group
  - 10-week hybrid group vs THR

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**Barn Activity (BA) group**
**Current Study Methods**

**Participant Inclusion Criteria**

<table>
<thead>
<tr>
<th>Inclusion</th>
<th>Exclusion</th>
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<tbody>
<tr>
<td>Ages</td>
<td>6 – 16.11 yrs</td>
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<tr>
<td>NVIQ</td>
<td>≥40</td>
</tr>
<tr>
<td>ABC-C</td>
<td>≥5</td>
</tr>
<tr>
<td>Diagnoses</td>
<td>ASD &amp; Psychiatric (Mood, Anxiety, ADHD)</td>
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<td># children per family</td>
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</tr>
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</table>

**Participant steps to 10-week study intervention**

1. **Phone Screen**: Clinic consent & screening tests
2. **Screen visit I**: Riding Center Screening
3. **Screen visit II**: Speech sample
4. 1 month prior to start: Speech sample
Participant steps after 10-week study intervention

1-month post-intervention: Speech Visit
6-month post-intervention: Speech Visit, THR and BA only
Participation Complete

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

Collection numbers as of Spring 2023
Therapeutic Horseback Riding N = 52
Barn Activity N = 34
Waitlist N = 25
Hybrid Activity N = 15

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

Population demographics as of January 2023
N = 163
*Data includes all consented individuals

<table>
<thead>
<tr>
<th>Age</th>
<th>Biological Sex</th>
<th>ADOS Severity</th>
<th>IQ</th>
<th>ABC-Irritability</th>
<th>BC Pervasive</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Male: 64% Female: 36%</td>
<td>4 (High)</td>
<td>86 (45-136)</td>
<td>13 (all required for medication trials)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>White/Caucasian</th>
<th>Black or African American</th>
<th>Native American or Alaska Native</th>
<th>Native Hawaiian or Other Pacific Islander</th>
<th>Other/Multi</th>
<th>Unknown/Not Reported</th>
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<tbody>
<tr>
<td>124</td>
<td>5</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>13</td>
<td>18</td>
</tr>
</tbody>
</table>

Incomplete or Cell Not Applicable: 24
Autonomic Bio Signals of Arousal/Stress: Wearable Physiological Sensors

**Electrodermal Activity (EDA)**
(Skin surface temperature)
- Sympathetic autonomic nervous system arousal response (reactivity and recovery) mediator:
  - Attention
  - Information processing
  - Emotion
- Low EDA = Calm state

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

**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

**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
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

Skilled Instructors Environment Setting the Stage for Success Manualized Approach

- Skilled Instruction
- Setting the Stage
- Manualized Approach

Manualized Approach

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

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

<table>
<thead>
<tr>
<th>Consistent intervention elements</th>
<th>Elements that can vary</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 minute learning activities + 20 minute wrap-up activities</td>
<td>Teaching activities may vary by individual performance and group learning needs</td>
</tr>
<tr>
<td>7 week themes per manual</td>
<td>Teaching activities may vary by individual performance and group learning needs</td>
</tr>
<tr>
<td>Routine/Structure:</td>
<td>Teaching activities may vary by individual performance and group learning needs</td>
</tr>
<tr>
<td>45-minute:</td>
<td>Teaching activities may vary by individual performance and group learning needs</td>
</tr>
<tr>
<td>• Beginning:</td>
<td>Teaching activities may vary by individual performance and group learning needs</td>
</tr>
<tr>
<td>• Middle:</td>
<td>Teaching activities may vary by individual performance and group learning needs</td>
</tr>
<tr>
<td>• Closing:</td>
<td>Teaching activities may vary by individual performance and group learning needs</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Volunteering involvement is critical</td>
<td>Visual cuing &amp; behavior management may vary based on individual needs/behavior goals and prompting in-hand change</td>
</tr>
<tr>
<td>Environment</td>
<td>Site-specific environment differences</td>
</tr>
<tr>
<td>Teaching Techniques for ASD population</td>
<td>Visual cuing &amp; behavior management methods may vary based on individual needs/behavior goals and prompting in-hand change</td>
</tr>
<tr>
<td>Visual cuing &amp; behavior management methods may vary based on individual needs/behavior goals and prompting in-hand change</td>
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</tr>
<tr>
<td>Site-specific environment differences</td>
<td>Site-specific environment differences</td>
</tr>
</tbody>
</table>

### Daily Schedules

<table>
<thead>
<tr>
<th>Time</th>
<th>THR Class Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00</td>
<td>Put on Equipment</td>
</tr>
<tr>
<td>9:15</td>
<td>Art Activity &amp; Cortical Stairs</td>
</tr>
<tr>
<td>9:30</td>
<td>Pause</td>
</tr>
<tr>
<td>9:45</td>
<td>Art Activity &amp; Cortical Stairs</td>
</tr>
<tr>
<td>10:00</td>
<td>Lunch &amp; Relax</td>
</tr>
<tr>
<td>10:15</td>
<td>Horse Care &amp; Petting</td>
</tr>
</tbody>
</table>
THR and BA modules follow the same themes

~ Examples of Module Similarities ~

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

BA Group: Week 3 – Anatomy of a Horse

THR Group: Week 3 – Listening to our Horse & Anatomy

Comparative Anatomy

Seeking to reach the different parts of the horse
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
Questions?

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