

# Horses and Humans Research Foundation Midway Grant Reporting

## “The Feasibility, Acceptability, and Preliminary Efficacy of a Manualized Equine-assisted Occupational Therapy Intervention for Children with Autism”

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### Summary of Progress

We consented and enrolled 24 children with autism and their caregivers in the study; 12 children in Northern Colorado and 12 children in Denver Metro area. Children were randomized to the treatment group or the waitlist control group. In Spring of 2019, children in the treatment group received 10 weeks of equine-assisted occupational therapy (OT), while children in the waitlist control group received 10 weeks of nature-based OT in a garden environment. In Summer 2019, children in the waitlist control group received equine-assisted OT. Preliminary outcomes are reported below, organized by study aim.

#### *Aim 1: Feasibility of Implementation*

One participant dropped from the study after being assigned to the control group; the remaining 23 participants are still enrolled in the study. In the fall group, 11 of the 12 participants attended 8 or more equine-assisted OT sessions. Eight of the 11 waitlist control group participants attended 8 or more nature-based OT sessions.

All 23 caregivers of children who completed the Spring intervention completed assessment measures; 21 of them completed the assessment measures within the preferred timeframe. Fifteen blinded raters completed the assessment measures for Time 1 and Time 2; fourteen completed within the preferred timeframe.

#### *Aim 2: Acceptability of Equine-assisted OT*

In the fall group, 11 of 12 caregivers were either satisfied or very satisfied with their child's participation in equine-assisted OT. The 12<sup>th</sup> caregiver was neutral.

#### *Aim 3: Preliminary Efficacy*

Children in the Spring treatment group demonstrated improvements in overall social functioning, particularly in the domains of social communication and social motivation. Children in the Spring waitlist control group demonstrated very slight decreases in overall social functioning, including in the domains of social communication and social motivation. Children in both the treatment and control groups demonstrated improvements in irritability and hyperactivity, although it is too soon to tell if one group improved more than the other. Generally, ratings provided by the blinded rater were positively correlated with ratings provided by the caregiver.

In regards to hair cortisol concentration, we collected 100% of hair samples for Time 1 and Time 2. Time 3 hair sample collection is still occurring. Hair samples will be sent to the lab for analysis in September 2019.

## Updated Time Line

	Nov '18	Dec '18	Jan '19	Feb '19	Mar '19	Apr '19	May '19	Jun '19	July '19	Aug '19	Sep '19	Oct '19– Apr '20
Recruitment & screening	Complete											
Riding screen & OT evaluation				C								
Pre-test data collection					C							
Treatment group EAOT					Complete							
Waitlist control group garden trips					Complete							
Time 2 data collection							C					
Treatment group garden trips								Complete				
Waitlist control group EAOT								Complete				
Time 3 data collection										IP		
Focus groups											Planned	
Data analysis & manuscript prep												Planned

**November, 2018 – February, 2019:** Recruitment and initial screening- COMPLETE

**February 1 - February 15, 2019:** Riding screening & OT Evaluation- COMPLETE

**February 16 – March 2, 2019:** Pre-test: initial efficacy assessment- COMPLETE

**March 5 – May 14, 2019:\*** EAOT (treatment group) + garden trips (waitlist control group)- COMPLETE

**May 15 – May 31, 2019:** Time 2: Second efficacy assessment; acceptability for treatment group- COMPLETE

**May 30 – August 12, 2019:\*** EAOT (waitlist control group) + optional garden trips (treatment group)- COMPLETE

**August 7 – August 20, 2019:** Time 3: Final efficacy assessment; acceptability for waitlist control group- IN PROGRESS (IP)

**September, 2019:** Focus groups with therapists- PLANNED

**October 2019 – April 2020:** Data analysis and manuscript preparation- PLANNED

\*Due to either school schedules or horse concerns, both Spring and Summer sessions of equine-assisted OT were extended from 10 weeks to 11 weeks. This pushed back our study timeline by 2 weeks from the original plan. See more details in subsequent sections.

# Budget

## Expenditures to Date

	Description	Cost / Unit	Units	Total
Personnel	~Occupational Therapy Student 1: Spring	\$385.32	1	\$385.32
	~ Occupational Therapy Student 2: Spring	\$385.32	1	\$385.32
	~ Occupational Therapy Student 3: Summer	\$276.48	1	\$276.48
	PERSONNEL TOTAL			\$1,047.12
Permanent Equipment	PERMANENT EQUIPMENT TOTAL			\$0.00
Consumable Supplies	*Waitlist Control Botanic Garden Supplies	\$499.37	1	\$499.37
	CONSUMABLE SUPPLIES TOTAL			\$499.37
Consultant Costs	Biostatistician	\$200	10	\$2,000.00
	CONSULTANT COSTS TOTAL			\$2,000.00
Travel	~Travel Reimbursement for Initial and Second Screening	\$0.49	1,363.25	\$667.99
	TRAVEL TOTAL			\$667.99
Client-related Expenses	~Hearts and Horses equine-assisted OT Sessions	\$155	85	\$13,175.00
	~My Heroes equine-assisted OT Sessions	\$155	114	\$17,670.00
	*Hearts and Horses Screening & Evaluation Visits	\$197.50	12	\$2,370.00
	*My Heroes Screening & Evaluation Visits	\$197.50	13	\$2,567.50
	~Waitlist Control Botanic Garden Passes	\$90	4	\$360
	CLIENT-RELATED EXPENSES TOTAL			\$36,142.5
Horse Expense	HORSE EXPENSE TOTAL			\$0.00
Total				\$40,356.98

## ~Expenditures Lower than Original Budget

- Occupational Therapy Student Salaries.** We budgeted to pay occupational therapy students \$2,400, a portion of the original budget item “Control Condition Trips to Botanic Gardens” in the Client-related Expenses section. We recruited and trained 6 students to run the control groups. Three of these students were fieldwork students, so they were compensated with credit and did not receive financial compensation. The Summer control group did not have as many participants, and therefore did not require as many hours. Actual cost of occupational therapy student salaries was \$1,047.12, a total savings of \$1,352.88
- Travel Reimbursement for Initial and Second Screening Visits.** We budgeted to reimburse 54 participants for 50 miles of travel each for the first and second screening visits; therefore, we budgeted \$1,421 to reimburse participants for 2,700 miles. Actual cost was only \$667.99, for a savings of \$753.01.
- Hearts and Horses Equine-assisted OT Sessions.** We budgeted to pay Hearts and Horses \$18,600 to provide 120 equine-assisted OT sessions. Due to 1 dropped participant, attendance rates, and a few cancelled sessions (described in next section), they only provided 85 equine-assisted OT sessions. Actual cost was \$13,175, for a savings of \$5,425.
- My Heroes Equine-assisted OT Sessions.** We budgeted to pay My Heroes \$18,600 to provide 120 equine-assisted OT sessions. Due to attendance rates and a few cancelled sessions (described in next section), they only provided 114 equine-assisted OT sessions. Actual cost was \$17,670, for a savings of \$930.
- Waitlist Control Denver Botanic Garden Passes.** We budgeted for entrance into gardens to cost \$2,400, a portion of the original budget item “Control Condition Trips to Botanic Gardens.” Northern Colorado garden trips were moved to CSU occupational therapy gardens, which is free of cost (reason for change described in next section). Denver trips occurred at Denver Botanic Gardens. To pay for entrance to Denver Botanic Gardens, we purchased 4 Family & Friends Passes, which allowed for

entrance of all participants and caregivers. Overall, actual cost for entrance into gardens was \$360, a savings of \$2,040.

**\*Expenditures Higher than Original Budget**

- 1. Waitlist Control Group Botanic Garden Supplies.** Given the lower than expected cost of the garden control group, we re-allocated some of these funds to purchase supplies for the control group. Supplies included art supplies for garden-related art activities (clay, paint, paper, crayons, glue, etc.), materials to facilitate gross motor games in the gardens (cones, dots, jump ropes, hula-hoops, balls, etc.) and planting supplies (seeds, soil, pots, etc.). This was an additional expense of \$499.37.
- 2. Screening and Evaluation Visits.** At the beginning of the study, occupational therapists requested that they receive their standard \$85/hour compensation rate for all study-related activities (at first, compensation rates varied based on different activities). This increase in compensation for occupational therapists in the study led to an increased per-visit rate for the screening and evaluation visits, from \$155 to \$197.50. Total increased cost was \$597.50 more than originally budgeted.

*Remaining Approved Expenses*

	Description	Cost / Unit	Units	My Estimate
Consumable Supplies	Leiter-3 Forms (20 Forms)	\$ 75.00	2	\$ 150.00
	SCQ Score Forms (pack of 20)	\$ 44.00	2	\$ 88.00
<b>TOTAL</b>				<b>\$ 238</b>

*Request for Approval for Additional Budget Items*

	Description	Cost / Unit	Units	My Estimate
Personnel	GAS Independent Rater	\$ 1,093.44	1	\$ 1,093.44
	PERSONNEL TOTAL			\$ 1,093.44
Consumable Supplies	ABC-2 Score Forms (50 forms)	\$ 64.00	3	\$192.00
	ABAS-3 School Age Parent Forms (25 forms)	\$ 81.25	1	\$81.25
	SRS-2 Child/Adolescent Forms (25 Forms)	\$ 52.50	3	\$157.50
	Focus Group Transcription	\$ 300.00	2	\$600.00
	ADOS-2 Protocol Booklets (pack of 10)	\$ 57.00	3	\$171.00
	Hair Cortisol Content Assays	\$ 42.00	58	\$2,436.00
	CONSUMABLE SUPPLIES TOTAL			\$3,637.75
Travel	Uber rides to EAOT for 1 participant	\$ 418.70	1	\$ 418.70
	TRAVEL TOTAL			\$ 418.70
Client-related Expenses	Therapist Compensation for Training	\$ 340.00	5	\$1,700.00
	Therapist Compensation for Focus Group	\$ 127.50	5	\$637.50
	Therapist Compensation for Feasibility Survey	\$ 21.25	5	\$106.25
	Blinded Rater Incentives for Surveys Time 1	\$ 20.00	16	\$320.00
	Blinded Rater Incentives for Surveys Time 2	\$ 20.00	13	\$260.00
	Blinded Rater Incentives for Surveys Time 3	\$ 20.00	8	\$160.00
	Caregiver Incentives for Outcome Assessments	\$ 15.00	70	\$1050.00
CLIENT RELATED EXPENSES TOTAL			\$4,233.75	
<b>TOTAL</b>				<b>\$ 9,383.64</b>

*Budget Justification*

Given that the original budget requested from the Horses and Humans Research Foundation is currently almost \$10,000 under-budget, we would like to request approval for additional budget items that were originally planned to be funded by seed money given to the Temple Grandin Equine Center by the Carl and Caroline Swanson Foundation. A budget justification for each of these items is given below.

## **PERSONNEL**

**GAS Independent Rater:** An occupational therapist research assistant was hired to independently rate participants' goal attainment. The research assistant was paid a salary of \$960 plus fringe benefits for rating participants' goals at time 2 and time 3, for a total cost of \$1,093.44.

## **CONSUMABLE SUPPLIES**

**ABC-2 Score Forms:** To be eligible for the study, children must score 32 or higher on combined irritability and hyperactivity subscales. Assuming 2/3 of screened participants are included, we may use up to 36 forms to screen and enroll 24 participants. After enrollment, participants' caregivers and teachers will each complete the ABC-2 three times: pre-test, Time 2, and Time 3. Therefore the study will require 180 ABC-2 score forms (24 participants x 2 raters x 3 time points = 144 + 36 screening forms = 180). Forms are sold in packs of 50, and our lab already owns 30 forms. Therefore, three packs of 50 will be bought for the study.

**ABAS-3 School Age Parent Forms:** The Adaptive Behavior Assessment System, Third Edition (ABAS-3) will be used to document the adaptive functioning of children with ASD that participate in the study. We will need 24 forms to complete the study; forms are sold in pack of 25, so we will buy one pack of forms. Dr. Susan Hepburn at Colorado State University owns an ABAS-3 manual that will be used for administration, scoring, and interpretation

**SRS-2 Child/Adolescent Handscore Forms:** The SRS-2 will be administered to each participant's caregiver and blinded rater three times: pre-test, Time 2, and Time 3. Therefore, 144 forms will be needed to complete this study (24 participants x 2 raters x 3 time points); forms are sold in packs of 25, so six packs of score forms will be purchased. Dr. Susan Hepburn owns the SRS-2 manual which will be used for administration, scoring, and interpretation.

**ADOS-2 Protocol Booklets:** To be eligible for the study, children must meet clinical cut-offs for ASD on the ADOS-2. The ADOS-2 will be administered at the initial screening visit, for all participant that do not have documentation of previous ADOS scores. Forms are sold in packs of 10, so three packs will be purchased. We will purchase 1 pack of Module 1, one pack of Module 2, and one pack of Module 3; our lab has access to additional forms if more than 10 forms of a specific module are needed. Dr. Susan Hepburn owns the ADOS-2 manual and supplies, which will be used for administration, scoring, and interpretation.

**Hair Cortisol Content Assays:** The Behavioral Immunology and Endocrinology Laboratory will conduct 58 assays of hair samples. Each assay costs \$42, for a total of \$2,436.  $\$42 \times 58 \text{ assays} = \$2,436$

**Focus-group Transcription:** Audiotaped focus groups will be transcribed by Franklin Square Services, which charges \$0.21 / line. The company estimates a 60-minute focus group will cost \$140 - \$220 to transcribe. Therefore, we estimate that a 1.5 hour focus group will cost about \$300 to transcribe. We will conduct one, 1.5-hour focus group at each center, for a total of \$600.  $\$300 \times 2 \text{ focus groups} = \$600$

## **TRAVEL**

**Uber Rides to Equine-assisted OT for 1 Participant.** There is currently extensive construction occurring around the Temple Grandin Equine Center that prohibits easy access to the center using public transportation. One participant in the study was completely reliant on public transportation, so could not access the center. We paid for 10 "Uber Health" rides to and from Temple Grandin Equine Center, so that this participant could still participate in the study. Overall, these Uber Health rides cost \$418.70.

## **CLIENT-RELATED EXPENSES**

**Therapist Compensation for Training:** Therapists were compensated \$340 for attending a training on how to implement the occupational therapy evaluation, including how to set and scale goal for Goal Attainment Scaling.  $\$340 \times 5 \text{ therapists} = 1,700$ .

**Therapist Compensation for Focus Group:** Therapists will be compensated \$127.50 in cash for attending 1.5 hour focus group at the end of the intervention. If all 5 therapists attend, a total of \$637.50 will be distributed to therapists.  $\$127.50 \times 5 \text{ therapists} = \$637.50$ .

**Therapist Compensation for Feasibility Survey:** Therapists will be compensated \$21.50 for completing a 15-minute survey about the feasibility of the equine-assisted OT intervention. If all 5 therapists complete the survey, a total of \$106.25 will be distributed to therapists.  $\$21.25 \times 5 \text{ therapists} = \$106.25$

**Blinded Rater Cash Incentives for Outcome Assessments:** Blinded raters are provided with a \$20 Amazon gift cards for completing the online survey. At Time 1, sixteen blinded raters completed the survey. At Time 2, thirteen blinded raters completed the survey. At Time 3, we expect up to 8 blinded raters will complete the survey. Therefore, up to \$740 worth of Amazon gift cards will be purchased for blinded raters.

**Caregiver Cash Incentives for Outcome Assessments:** Caregivers will be provided with \$15 in cash for each time they complete outcome assessments. Caregivers will be asked to complete outcome assessments three times. After the first outcome assessment, one participant dropped from the study. Therefore, if all 24 caregivers complete the first assessment, and 23 caregivers complete the second and third assessments, a total of \$1,050 will be distributed to caregivers.  $\$15 \times 70 \text{ outcome assessments} = \$1,050$ .

## Summary of any complications or challenges that have been encountered and how they have been or are being addressed.

1. The control group in Northern Colorado was originally planned to occur at Spring Creek Gardens, a botanic garden in Fort Collins. However, upon receiving funding for the study we learned that Spring Creek Gardens would be under construction and not open to the public during Spring 2019. Therefore, we relocated the Northern Colorado control group to the Occupational Therapy gardens on CSU's campus, and bought some additional therapy supplies to facilitate these groups. Due to the relocation, children were able to plant their own garden bed, and taste some of the vegetables they grew.
2. There were several scheduling concerns that caused us to reschedule a few sessions, described in detail for each location. Despite these challenges, all participants were still offered either 9 or 10 sessions of equine-assisted OT. While we recognize 9 sessions instead of 10 is not ideal, our pilot data demonstrate that significant changes begin to occur in participants after 5 weeks of equine-assisted OT, so we do not believe it will affect study outcomes.
  - a. **Spring Control Group Northern Colorado.** There were 3 snow days on Wednesdays in Spring 2019 that caused us to cancel 3 of the nature-based OT sessions in Northern Colorado. We were able to fit in one make-up day. We could not add additional make-up days because the students who were running the group graduated and left for a different fieldwork. Therefore, only 8 sessions of nature-based OT were offered to the waitlist control participants in Northern Colorado.
  - b. **Spring Equine-assisted OT Group Northern Colorado.** Three of the six participants were cancelled on April 26 due to therapist illness. We were not able to reschedule an additional session without compromising the study timeline, as the Northern Colorado group was already 1 week behind the Denver group due to their Spring Break schedule. Therefore, three northern Colorado participants were offered 9 sessions of equine-assisted OT, and three northern Colorado participants were offered 10 sessions of equine-assisted OT.
  - c. **Spring Equine-assisted OT Group Denver.** There was a snow day during one scheduled equine-assisted OT session in Denver. We were not able to add an additional week to the end of the 10-week session due to lack of staff, so participants in this group were offered 9 weeks of equine-assisted OT.
  - d. **Summer Equine-assisted OT Group Northern Colorado.** We pushed back the 10-week session by one week, so that all children would be out of school by the beginning of the session. There was an outbreak of vesicular stomatitis that infected all of the horses at Hearts and Horses in Summer 2019, causing us to cancel 2 weeks of equine-assisted OT at Hearts and Horses. We were able to reschedule one of these sessions to My Heroes in Northern Colorado. We also added an additional week to the end of the session. Therefore, participants in this group were offered 9 weeks of equine-assisted OT.
  - e. **Summer Equine-assisted OT Group Denver.** Temple Grandin Equine Center unexpectedly lost two horses in their relatively small herd before the Summer session began. Therefore, we made the determination that all 6 equine-assisted OT sessions could not be held on the same day, due to the changes in horses available for the study. We moved half of the equine-assisted OT sessions to Mondays, and kept the other half on Thursdays. We added an additional week to the end of the 10-week session to accommodate this change. All participants in this group were offered 10 weeks of equine-assisted OT.
3. One of our participants informed us she was not able to access the Temple Grandin Equine Center using public transportation due to the construction occurring near the facility. Therefore, we scheduled and paid for Uber Health rides to and from the facility, so she could continue participation in the study.