

CREIGHTON UNIVERSITY PARENTAL PERMISSION

Protocol Title: Effectiveness of a 6-week hippotherapy program in children with autism spectrum disorder

IRB project number: 2000065

Sponsor: National Institute of Health

Principal Investigator's Name and Department: Anastasia Kyvelidou, Physical Therapy

Principal Investigators': Telephone Number: 402-280-5749

Research Investigators' Names and Departments: Kirk Peck, Physical Therapy; Dimitrios Katsavelis, Exercise Science and Health Professions; Edye Godden, Heartland Equine Therapeutic Riding Academy (HETRA).

24-Hour Telephone Number: 401-323-3861

Study Summary

We invite you to bring your child to participate in a study looking at the effectiveness of a 6-week treatment program on a horse at the Heartland Equine Therapeutic Riding Academy ("HETRA"). The study involves being evaluated before and after a 6 week/once per week treatment program, and 3 evaluations during the sessions with the horse (1st, 3rd and 6th session).

Important things to know:

- Taking part in research is voluntary. You can choose not to be in this study or stop at any time.
- If you decide not to be in this study, your choice will not affect your any services you receive or your relationship with the investigators of this study. There will be no penalty to you.
- You don't have to be in this study to get care for your health condition.
- Therapy with the horse can be available to you and your child regardless of your participation in the study.

If you agree to participate in this study;

- Thirty children between the ages of 5-10 will be involved in this study.
- Eight number of visits are required.
- These visits will take 8 hours in total.
- The potential benefits of participating in this study are, reports on your child's movement and social behavior, and riding horses.
- You will also be required to sign the consent by the Heartland Equine Therapeutic Riding Academy.
- The potential risks to be in this study are falls, stress, fatigue, allergies, horse bite and horse kick.

		
	Approved:	January 18, 2021
	Study Number:	2000065

Introduction

Your child has been invited to participate in this research because:

- He/she is between 5-10 years of age
- Is developing typically
- Is diagnosed with Autism Spectrum Disorder (ASD)
- Can tolerate a helmet and wearing movement and heart rate sensors.

Your child will also need to receive medical approval by your health care provider/pediatrician/family physician to participate in the therapy sessions with the horse and not to have any other medical or psychiatric diagnoses besides ASD. If your child is under 5 years of age or over 10 years of age, has a serious comorbid medical diagnosis, major vision or hearing impairments, severe behavioral problems or an orthopedic or genetic diagnosis, they cannot participate in this study. Examples of genetic diagnoses are Fragile X syndrome, Rett syndrome and Tuberous Sclerosis Complex. Children participating in the study will come to the Heartland Equine Therapeutic Riding Academy 8 times and participate in the study activities where data will be collected. Each data collection visit will not take more than an hour. Please ask any questions or express any concerns you or your child may have regarding this research study before deciding whether your child will participate. Contact information for the study investigator (Anastasia Kyvelidou) is listed above.

Name of Participant: _____

If you are signing this Consent on behalf of someone else, all references from this point forward to “you” or “your” will mean the Study Participant named above.

Study Purpose and Procedures

- This study involves research
- This project aims to determine the effects of a 6-week therapy program with a horse on movement and social behavior of children with and ASD, and to investigate how effectiveness of treatment is related to the movement coordination of the child and the horse as well as the heart rate coordination between the child and the horse.
- Your child is expected to participate in 8 visits to HETRA that will take approximately one hour each.
- You will complete an intake form that will include height and weight of your child, information about birth weight and gestational age at the time of his or her birth, and a series of questions with respect to whether your child is eligible to participate in the research study.

Then the first and last visits will include:

- Social play in which the principal investigator, a student, and caregivers will engage in 10-minute semi-structured play interactions with your child. The study personnel will provide

		
	Approved:	January 18, 2021
	Study Number:	2000065

board games, building blocks, books, and similar age-appropriate toys depending upon the age of your child. This session will be videotaped for subsequent analysis.

- Standing posture assessment, in which your child will be asked to stand as still as possible for 20 seconds with their arms at their sides and facing a bare wall. Children will perform 4-6 trials of standing with eyes open and eyes closed (2-3 with eyes open and 2-3 with eyes closed).
- You will be asked to fill out a survey that examines the alertness, emotional reaction, level of interest and attention, comfort level around strangers, level of activity, overall level of communication, and play behavior of the child.
- You will be asked to fill out 2 questionnaires that examine the behavior of your child in terms of autism symptoms, irritability and speech.

Therapy sessions (Visits 2 – 7)

- During these visits your child will be asked to perform different movement tasks while being on the horse. For example, raising hands, touching the back of the saddle, clapping, etc. During these sessions the horse will be walking in a slow and comfortable pace around the barn. There will be one horse guide that will control the horse and walk in front of it, two spotters (one on each side of the horse, next to your child) and the occupational therapist that will give instructions to your child on what to do. For all therapy sessions with the horse your child must always wear a helmet.
- During the 2nd, 4th, and 7th visit your child will be asked to participate in the therapy session on the horse while:
- Wearing a helmet and two straps (1 around the chest and 1 around lower back) that will have movement sensors on them, like the apple watch, and one strap around the chest to record your child's heart rate.
- During the 3rd, 5th and 6th visit your child will only participate in the therapy sessions on the horse with no electronic data being acquired.



Here is an example of the movement sensor that is placed on the chest of the child

Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8
Procedures	-Social Play -Standing	Therapy on the horse	Therapy on the horse	Therapy on the horse	Therapy on the horse	Therapy on the horse	Therapy on the horse	-Social Play -Standing posture

		
	Approved:	January 18, 2021
	Study Number:	2000065

	posture -Survey -Questionnaires	-Movement sensors -Heart rate monitor	No data collected	-Movement sensors -Heart rate monitor	No data collected	No data collected	-Movement sensors -Heart rate monitor	-Survey -Questionnaires
--	---------------------------------------	--	----------------------	--	----------------------	----------------------	--	----------------------------

During the 8 weeks participating in this study you will not be able to engage in horseback riding activities outside of the study.

Benefits of Participating in the Study

A child involved in the study may or may not benefit by receiving free therapy sessions on the horse. You will also receive reports of your child's social, and movement behavior as part of the protocol.

Risks of Participating in the Study

- Risks and discomforts related to this study are greater than minimal, and include stress, allergies, fatigue, falls, horse bite and horse kick.
- To minimize the risks related to experiments with children pre and post data will be collected in a comfortable room located next to the barn at HETRA. Moreover, these risks will be also minimized as follows: 1) If the child becomes fussy, rest will be provided, or a snack will be allowed during pre and post evaluations, 2) Data collection will only proceed if the child is in a calm and alert state, and 3) The child's parent will be at the child's side, within touching distance throughout the pre and post sessions. During the therapy sessions on the horse, spotters at each side of the horse are present to ensure that the child will not fall and there is a horse guide that controls the horse.
- The confidentiality risks encountered during the study are minimal. All data and personal information collected from children for this study will be labeled with code numbers. Videos of the sessions will be securely located in computers or servers that are password protected.
- A possible risk involved in this study is the potential social and psychological risks associated with accidental disclosure of confidential information from the data collected throughout the study. Methods of storing and securing data are designed to minimize this risk.

Confidentiality

We will do everything we can to keep your child's records confidential. However, it cannot be guaranteed. We may need to report certain information to agencies as required by law. The records we collect identifying you as a participant will be maintained and stored at Creighton University. The study involves video recording as part of this study's procedures. The purpose of this video is to monitor your child's movements for the analysis of the data. The recordings will be stored in a secure server at Creighton University. If you decide to withdraw from the study before completion, any data or video will be destroyed. If you complete the study the videos and data collected will remain in our server. The videos will be destroyed within 5 years of the completion of the study.

		
	Approved:	January 18, 2021
	Study Number:	2000065

Records that identify you and this consent form signed by you may be looked at by others. The list of people who may look at your research records are:

- The investigator and his or her research staff and students.
- The Creighton University Institutional Review Board (IRB) and other internal departments that provide support and oversight at Creighton University.
- Videos of the therapy on the horse maybe viewed by the Creighton University's Institutional Animal Care and Use Committee (IACUC).
- We may present the research findings at professional meetings or publish the results of this research study in relevant journals. However, we will always keep your name and other identifying information private.

We will also ask you to sign a separate form called the HIPAA Authorization, which will give you more specific information concerning the use of your health information.

Disclosure of Potential Future Use of private information

- This study involves the collection of private information (name, dates, medical record numbers etc.). Even if identifiers (name, dates, medical record numbers etc.) are removed, information collected as part of research will not be used or distributed for future research studies.

Disclosure of Appropriate Alternatives

Instead of being in this research study, as an alternative to participation, you can choose not to allow your child to be in this study. Choosing not to participate in this study will not adversely impact your right to services otherwise available to you at HETRA or Creighton University.

Compensation for Participation

- There will not be compensation associated with participation in this study.

Contact Information

Please contact the primary research investigator, Anastasia Kyvelidou, with any questions or concerns regarding this research study at:

Email: AnastasiaKyvelidou@creighton.edu

Personal Telephone: (401)323-3861

ADDITIONAL ELEMENTS

The investigators will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care at the usual charge. The costs of this care will be charged to you or to your health insurer. No funds are available from Creighton University or HETRA to

		
	Approved:	January 18, 2021
	Study Number:	2000065

repay you or compensate you for a study-related injury or illness. There is also no compensation available for payment of your lost wages or other losses.

By signing this consent form, you will not be waiving any of your legal rights that you otherwise would have as a participant in a research study.

Consequences of participant's Decision to Withdraw

You can stop your child's participation in this research (withdraw) at any time by speaking to the principal investigator and/or research investigators. Deciding to withdraw will otherwise not affect your or your child's care or relationship with the investigators, Creighton University or HETRA.

Research Results

You will receive reports of your child's social, and movement behavior as part of the protocol after the end of the 8 visits that will be mailed to you by the principal investigator.

SIGNATURE CLAUSE

You are free to refuse to participate in this research project or to withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled, or any effect on your medical care.

My signature below indicates that all my questions have been answered. I agree to participate in the project as described above.

Printed Name of (person signing)

Signature of (person signing)

Date Signed

The Creighton University Institutional Review Board (IRB) offers you an opportunity (anonymously if you so choose) to discuss problems, concerns, and questions; obtain information; or offer input about this project with an IRB administrator who is not associated with this particular research project. You may call or write to the Institutional Review Board at (402) 280-2126; address the letter to the Institutional Review Board, Creighton University, 2500 California Plaza, Omaha, NE 68178 or by email at irb@creighton.edu.

A copy of this signed form has been given to me. _____ participant's Initials

		
	Approved:	January 18, 2021
	Study Number:	2000065

For the Research Investigator—I have discussed with this participant (and, if required, the participant's guardian) the procedure(s) described above, and the risks involved; I believe he/she understands the contents of the consent document and is competent to give legally effective and informed consent.

Signature of Responsible Investigator

Date Signed

Bill of Rights for Research Participants

As a participant in a research study, you have the right:

1. To have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.
2. To refuse to be in the study at all, or to stop participating at any time after you begin the study.
3. To be told what the study is trying to find out, what will happen to you, and what you will be asked to do if you are in the study.
4. To be told about the reasonably foreseeable risks of being in the study.
5. To be told about the possible benefits of being in the study.
6. To be told whether there are any costs associated with being in the study and whether you will be compensated for participating in the study.
7. To be told who will have access to information collected about you and how your confidentiality will be protected.
8. To be told whom to contact with questions about the research, about research-related injury, and about your rights as a research participant.
9. If the study involves treatment or therapy:
 - a. To be told about the other non-research treatment choices you have.
 - b. To be told where treatment is available should you have a research-related injury, and who will pay for research-related treatment.

		
	Approved:	January 18, 2021
	Study Number:	2000065