PARENTAL PERMISSION FORM

Research Title: Physical therapy for Montana children with neuromotor disorders using hippotherapy and the equine environment

Sponsor: Montana IDeA Network for Biomedical Research Excellence (INBRE)

Investigator(s):

Julia Mazzarella, Physical Therapy, Julia.mazzarella@mso.umt.edu, 406-243-4684

Inclusion Criteria:

- Age 6-17 years;
- Diagnosed neuromotor disorder affecting at least one upper extremity;
- Able to follow simple instructions in English;
- Able to tolerate sitting on a horse continuously for 20 minutes;
- Meet Professional Association of Therapeutic Horsemanship International (PATH Intl.) standards for participating in mounted activities.

Exclusion Criteria:

- Weight over 175 lbs
- Lacking independent head control
- Fear or aversion to horses
- Having participated in a horseback-riding program in the past 6 months
- History of elopement
- History of uncontrolled seizures in past 12 months
- Caregiver unable to speak and read English

Purpose:

This is a study to determine if hippotherapy, where your child rides a horse as a component of their therapy, can improve the motor skills of the arms in children with neuromotor disorders (such as cerebral palsy, spinal muscular atrophy, or spina bifida). We will provide 16 biweekly 1-hour sessions of hippotherapy for 8 weeks to the treatment group. Participants in the control group will receive 16 sessions of standard play-based therapy. Both the treatment and control groups will continue with their regular outside therapies throughout the study duration. This study will also evaluate how horse and human interact during an equine-assisted rehabilitation session in terms of mood, movement, and physical responses like heart rate. The results will help us better understand how horses can help people in rehabilitation and will be shared at scientific meetings and in publications with other researchers and professionals in the field of equine-assisted rehabilitation.

Procedures:

If you agree to you and your child's participation in this study the Study Coordinator will schedule your first visit. During this first visit we will ask you to sign this consent form. We will then test your child's motor skills and ask you and your child to fill out a few standardized

University of Montana-Missoula
IRB-FY2024-330
Approved on 10-14-2026
Expires on 8-31-2030

questionnaires. The first visit will last about 2.5 hours and will include breaks for your child as needed.

Your child will be randomly assigned to either the hippotherapy or play-based control group. "Randomly assigned" means that each subject will be picked by chance, like tossing a coin or drawing straws, to participate in one of the treatment groups. Each participant has a 50/50 chance of being assigned to each group.

Participants in the hippotherapy group will be receiving therapy at either Trotting Horse Therapeutic Riding in Missoula, MT. Participants in the play-based control group will receive therapy at Samara Therapy Specialists in Missoula. It is important to have consistent attendance at therapy sessions. You will be asked to sign a "Therapy Attendance Agreement" and you may be asked to make up missed sessions while your child is participating in this study.

We will video record your child's therapy sessions and assessment visits during this study. This will be done to make sure that all of the study therapists provide therapy and assessments the same way.

All information collected for this study, including the forms that you fill out and study logs, will be kept in a locked, secure cabinet with access only to the study staff. Information will also be entered and saved in a secure database.

Additional measures of human-equine interaction will be collected in 4 of the treatment sessions. Your child will be asked to provide a sample of their saliva at the beginning and end of 4 of the treatment sessions by drooling into a tube. Your child will also be asked to wear a heart monitor on a strap around their chest for the entire session. Your child will be asked to answer 4 questions about how they enjoyed the therapy.

Following the 8-week intervention, we will ask you and your child to return to the PALS Lab to repeat the testing of their motor skills and the questionnaires that you completed at the first visit. This final visit will last approximately 2 hours.

Payment for Participation:

You will receive $20 cash each for completing the pre- and post-assessments, as well as $5 per treatment session you attend to offset transportation costs, for a total up to $80 for attending all treatment sessions. The cash for transportation costs will be paid at the post-assessment. Your child will receive 16 hours of PT free of charge.

Risks/Discomforts:

The risks of participating in this study are the same as the risk associated with recreational horseback riding or standard physical therapy. There is a small chance that your child could fall off the horse or be bitten, kicked, or stepped on. We take several measures to mitigate these risks by providing a helmet, a skilled horse handler, and a side walker on either side of your child to maintain your safety while mounted on the horse. Muscle soreness may also occur as a result of being mounted on the horse, if this is a new activity for your child.

University of Montana-Missoula
IRB-FY2024-330
Approved on 10-14-2026
Expires on 8-31-2029

Benefits:

It is possible that your child will experience improvements in mood, strength, balance, coordination, postural control, range of motion, and voluntary motor control. Your child's participation in this study may help contribute to the understanding of how horses can benefit humans in rehabilitation.

Confidentiality:

Your child's records will be kept confidential and will not be released without your consent except as required by law. If the results of this study are written in a scientific journal or presented at a scientific meeting, your child's name will not be used. Media will be stored on an encrypted hard drive and hard copy records will be stored in a locked file cabinet only accessible by the study team. All identifying data will be destroyed following completion of study activities.

Voluntary Participation/Withdrawal:

Your decision to allow your child to take part in this research study is entirely voluntary. You may refuse to allow your child to take part in or you may withdraw your child from the study at any time without penalty or loss of benefits to which you or your child are normally entitled.

Your child may be asked to leave the study for any of the following reasons:

1. Failure to follow the Project Director's instructions;
2. A serious adverse reaction which may require evaluation;
3. The Project Director thinks it is in the best interest of your child's health and welfare; or
4. The study is terminated.

Future research:

Identifiers might be removed from the identifiable private information or identifiable biospecimens and could then be used for future research studies or distributed to another investigator for future research studies without additional parental permission from you or the child's legal guardian.

Disclosure of Personal Health Information:

I authorize *Julia Mazzarella* and the researcher's staff to use my child's individual health information for the purpose of conducting this research project.

My child's individual health information that may be used to conduct this research includes:

Demographic information, results of gross motor assessments, saliva test, and heart rate monitoring.

If my child receives compensation for participating in this study, identifying information about my child may be used as necessary to provide compensation.

Questions:

If you have any questions about the research now or during the study contact: Julia Mazzarella at 406-243-4684, or Jessica Rowe at 406-243-4709.

If you have any questions regarding your child's rights as a research subject, you may contact the UM Institutional Review Board (IRB) at (406) 243-6672.

University of Montana-Missoula
IRB-FY2024-330
Approved on 10-14-2026
Expires on 8-24-2029

Parent's Statement of Permission:

I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I voluntarily agree to have my child take part in this study. I understand that I will receive a copy of this permission form.

_____
Printed Name of Subject (Minor)

_____
Printed Name of Parent or Legally Authorized Representative

_____ _____
Signature of Parent or Legally Authorized Representative Date

Statement of Permission to be Photographed, Audiotaped, Videotaped, etc. [If applicable]

[Examples:]
I understand that photographs and audio/video recordings may be taken during the study.
I give permission for my child to be photographed and audio/video recorded.
I give permission for the use of my child's photograph and video in presentations related to this study.
I understand that if photographs and video recordings are used for presentations of any kind, names or other identifying information will not be associated with them.

_____ _____
Signature of Parent or Legally Authorized Representative Date

Compensation for Injury:

In the event that your child is injured as a result of this research you should individually seek appropriate medical treatment. If the injury is caused by the negligence of the University of Montana or any of its employees, you may be entitled to reimbursement or compensation pursuant to the Comprehensive State Insurance Plan established by the Department of Administration under the authority of M.C.A., Title 2, Chapter 9. In the event of a claim for such injury, further information may be obtained from the University's Risk Manager (406-243-2700; jason.sloat@mso.umt.edu) or the Office of Legal Counsel (406-243-4742; legalcounsel@umontana.edu). (Reviewed by University Legal Counsel, May 9, 2013)

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

University of Montana-Missoula
IRB-FY2024-330
Approved on 10-14-2026
Expires on 8-24-2029