

STUDY PROTOCOL

AND STATISTICAL ANALYSIS PLAN

OFFICIAL STUDY TITLE

Tiny Hooves, Big Impact - A Feasibility Study of Miniature Equine-Assisted Diabetes Education for Children with Diabetes

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PRINCIPAL INVESTIGATOR

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STUDY SITE

Nemours Children's Health, Jacksonville, Florida

Research Study Protocol Template

Study Protocol Title:

Tiny Hooves, Big Impact – A Feasibility Study of Miniature Equine–Assisted Diabetes Education for Children with Diabetes

List of Abbreviations:

- ☐ **ADAPT:** Adaptive Diabetes and Pony Therapy (program name)
- ☐ **ADA:** American Diabetes Association
- ☐ **DEEP:** Diabetes & Equine Empowerment Program
- ☐ **EAL:** Equine-Assisted Learning
- ☐ **EAT:** Equine-Assisted Therapy
- ☐ **ESMHL:** Equine Specialist in Mental Health and Learning (PATH Intl. certification)
- ☐ **CGM:** Continuous Glucose Monitor
- ☐ **A1C:** Glycated Hemoglobin (measure of average blood glucose)
- ☐ **PAID-C:** Problem Areas in Diabetes – Child version (survey instrument)
- ☐ **PAID-T:** Problem Areas in Diabetes – Teen version (survey instrument)
- ☐ **SCI-U:** Self-Care Inventory-Updated (survey instrument)
- ☐ **T1D:** Type 1 Diabetes
- ☐ **TIR:** Time in Range (glucose metric)
- ☐ **ISPAD:** International Society for Pediatric and Adolescent Diabetes

Principal Investigator, Research Team, and Study Site:

Principal investigator: Jennifer Pfeiffer, APRN

Co-Investigators: Susana R Patton, PhD; Monica Mortensen, DO, Keisha Bird, DNP

Research team and contact Information: Jennifer Pfeiffer, APRN

Study site: Jacksonville, FL

Research Synopsis

Study Title Tiny Hooves, Big Impact – A Feasibility Study of Miniature Equine–Assisted Diabetes Education for Children with Diabetes

IND Sponsor

N/A

Study Population

- 1) Youth ages 8–20 with diabetes; youth has not attended clinic in last 6 months or has A1C $\geq 9\%$; youth can follow instructions; youth is not allergic to horses and does not fear horses
- 2) Primary caregiver of youth who meet eligibility criteria

Study Design

Single-arm. pre–post feasibility study evaluating an educational intervention

Sample Size

Up to 36 participants

Study Duration

Up to 9 months

Study Agent and Intervention Description (If applicable)

ADAPT program (Miniature Equine–Assisted Diabetes Education): a four-session diabetes-specific psychoeducational program with miniature horses and led by certified staff.

Primary Objective

To assess the feasibility and acceptability of a miniature equine–assisted diabetes education program for youth with diabetes, and to explore its impact on diabetes distress and treatment related outcomes (e.g., engagement, appointment attendance, technology use).

Hypotheses

H1: DEEP is feasible if we achieve a recruitment rate $\geq 33\%$, retention rate $\geq 80\%$, and a session completion rate $\geq 75\%$.

H2: DEEP is acceptable if $\geq 80\%$ of youth/caregivers report high satisfaction and willingness to recommend DEEP to other youth/families.

Exploratory: Youth will show improvement in diabetes distress, adherence, and appointment attendance pre- to post-participation.

Background and Significance:

Youth with diabetes frequently experience psychosocial distress (diabetes distress), reduced adherence, and missed care that undermine glycemic control and well-being. Equine-assisted learning/therapy (EAL/EAT) has shown promise across pediatric groups—improving confidence, communication, emotional regulation, and engagement—but no published trials have tested miniature equine–assisted diabetes education in real-world clinical settings, nor evaluated feasibility/acceptability endpoints or diabetes-specific outcomes (self-care, appointment adherence, A1C/TIR). This leaves a practical knowledge gap regarding safety procedures, fidelity, and early signals of impact when equine activities are intentionally paired with diabetes education for youth. The present feasibility/acceptability study is designed to address this gap and generate preliminary evidence for subsequent controlled trials.

Nemours-specific outcome data for miniature equine–assisted diabetes education are not yet available; hence the initial single-arm feasibility/acceptability design. Preparatory work completed includes creation of : (a) age-stratified session modules and fidelity checklists (start/stop times, % planned activities completed, infection-control steps, deviations), (b) safety workflows (ESMHL-certified handlers, allergy/illness screening, hand hygiene/PPE, incident documentation), and (c) predefined feasibility benchmarks (recruitment $\geq 33\%$, retention $\geq 80\%$, session completion $\geq 75\%$) and acceptability benchmarks ($\geq 80\%$ satisfied/willing to recommend). Validated instruments (PAID-C/PAID-T; SCI-U) and routine diabetes-specific health indicators (A1C/TIR, technology uptake, appointment attendance) are included for pre/post/follow-up assessment to explore effects of the new program.

Objectives:

Primary Objective

To assess the feasibility and acceptability of a miniature equine–assisted diabetes education program for youth with diabetes, and to explore its impact on diabetes distress and treatment related outcomes (e.g., engagement, appointment attendance, technology use).

Study design/methodology:

Single-arm, **mixed-methods feasibility and acceptability** study conducted over one program cycle aligned with the school year (September–May). No investigational drugs/devices are used.

Eligible participants will be identified through EHR review, followed by outreach to confirm inclusion/exclusion criteria and obtain parental permission and youth assent in accordance with Nemours policy. At baseline, youth will complete age-appropriate measures of diabetes distress (PAID-C for ages 8–12 or PAID-T for ages 13–20) and self-care engagement (SCI-U); primary caregivers will complete the corresponding parent versions of the diabetes-distress measures (PPAID-C or PPAID-T) and a family demographic questionnaire. Participants will then take part in four age-tailored DEEP program sessions (20–30 minutes each), delivered monthly or every other month by an APRN and an ESMHL-certified handler and focused on rapport-building, mindfulness, problem-solving, leadership/advocacy, and transition skills. Following the final session, youth and caregivers will repeat the diabetes-distress and self-care measures and complete a brief satisfaction and recommendation survey. Up to six months after program completion, routine clinical indicators—including visit attendance, A1C, time-in-range (when available), and technology uptake (CGM or pump starts)—will be abstracted from the EHR

Study Population:

- 1) Youth ages 8–20 with diabetes; youth has not attended clinic in last 6 months or has A1C $\geq 9\%$; youth can follow instructions; youth is not allergic to horses and does not fear horses
- 2) Primary caregiver of youth who meet eligibility criteria

Inclusion /Exclusion Criteria

Include.

- Youth ages 8–20 with diabetes
- No clinic visit in the last 6 months OR A1C ≥ 9
- Able to follow instructions
- No allergies or fear of horses

Exclude.

- Severe behavioral issues
- Inability to participate safely
- Non-English Speaking

Study drug /Interventions:

ADAPT program (Miniature Equine–Assisted Diabetes Education): a four-session diabetes-specific psychoeducational program with miniature horses and led by certified staff.

Study Schedule:

- **Screening/Eligibility (Baseline):** EHR review and outreach; confirm inclusion/exclusion; obtain parental permission and youth assent per Nemours policy.
- **Pre-Program Surveys (Baseline):** youth complete PAID-C/PAID-T (based on youth age) and SCI-R. Primary caregiver complete PPAID-C/PPAID-T (based on youth age) and family demographics.

Problem Areas in Diabetes- Child (PAID-C) is a validated 11 item questionnaire to assess feelings of diabetes distress in children 8-12 year old.

Problem Areas in Diabetes- Teen (PAID-T) is a validated 14 item questionnaire to assess feelings of diabetes distress in teens 13-20 years old.

Parent Problem Areas in Diabetes- Child (PPAID-C) is a 16 item questionnaire to assess parents' perspective of diabetes distress. The PPAID-C is appropriate for parents of youth 8-12 years old.

Parent Problem Areas in Diabetes- Teen (PPAID-T) is a 15 item questionnaire to assess parents' perspective of diabetes distress. The PPAID-T is appropriate for parents of youth 13-20 years old.

Self-Care Inventory-Updated (SCI-U) is a validated 13 item questionnaire to assess perceptions of self-care treatment engagement.

- **Program Sessions (4 total; 20–30 minutes each; monthly or every other month):** Age-graded DEEP modules led by APRN and ESMHL-certified handler rapport/consent-to-touch, mindfulness before procedures, problem-solving, leadership/advocacy, transition planning.
- **Post-Program Surveys:** Repeat youth PAID-C/PAID-T and SCI-U; caregiver repeat the PPAID-C or PPAID-T. Youth and caregiver complete satisfaction & recommendation survey (Likert + free text).
- **Follow-Up (≤ 6 months post):** Abstract routine care attendance, A1C/TIR (when available), technology uptake (CGM/pump starts) from EHR.

Adverse Event Reporting:

This study involves minimal risk. The intervention consists of educational and mindfulness-based activities delivered by an APRN and an ESMHL-certified handler, with no medical procedures, medication changes, or physical activities beyond routine clinical care. As such, we do not anticipate any adverse events (AEs) or serious adverse events (SAEs) related to study participation. If an unexpected AE or SAE were to occur, study staff would follow standard Nemours clinical and research policies, including immediate assessment of participant safety, notification of the PI, documentation in REDCap, and reporting to the IRB within the required timelines. Any medical concerns would be managed by on-site clinical staff according to usual care protocols. Participation would be paused or discontinued if continuation posed any risk to the participant.

Statistical Analysis Plan:

- **Primary Outcomes:** We will compute mean $\pm$ SD and frequency counts to examine our recruitment and retention rates, session completion rates, and session fidelity. We will use frequency counts and a one sample t-test to test if $\geq 80\%$ of youth report that they were satisfied with their participation in DEEP.
- **Secondary Outcomes:** We will use paired sample t-test or Wilcoxon sign test (for non-normal distribution) to examine changes in youths' report of DD and SCI-R scores pre- to post-treatment. We will also use paired sample t-test or Wilcoxon sign test to examine changes in youths' A1C or TIR pre- to post-treatment. We will use descriptive statistics (mean $\pm$ SD and frequency counts) to explore follow-up measures including % of routine T1D care visits attended in the 6 months following DEEP participation and number of T1D technology starts in

the 6 months following DEEP participation.

Sample size determination

- As a feasibility/acceptability pilot, a convenience sample of 24–36 participants is adequate to estimate process metrics and refine procedures.

Data Quality, Management, and Integrity:

After participants complete any study-related surveys, they will be automatically scanned by REDCap for completeness. If missing items are found, a study team member will follow up with the participant to determine if they declined to answer that particular question or if it was skipped by mistake. The study team will use a Data Tracking Form to track and monitor the completion of all questionnaires and other study measurements (e.g., medical record review). The Principal Investigator and the study team will review these tracking forms regularly in a separate study meeting dedicated to data quality and management

Informed Consent Process:

The informed consent and assessment process will be conducted by the Principal Investigator or trained study staff with experience in research consent procedures. In-person consent/assent will be obtained in a private setting at the clinic, either before or after a routine appointment, ensuring participants and families have sufficient time and privacy to consider participation. We may also obtain eConsent/eAssent remotely using secure, IRB-approved electronic methods to reduce burden when a clinic visit is not scheduled. Parents/caregivers and youth will be given ample time to review the consent/assent forms, ask questions, and discuss participation with family or others if desired. The process will include a thorough description of the study, a question-and-answer session, and a teach-back to confirm understanding.

For youth who are 18 years of age or older at study enrollment, informed consent will be obtained directly from the participant, and parental permission will not be required. For participants who turn 18 during the study, study staff will re-consent the individual at or near their 18th birthday using the adult consent form. Until re-consent is obtained, no additional study procedures will be conducted.

There is no pressure to decide immediately; families and participants may take the forms home and contact the study team later if they wish to participate. The consent/assent discussion will typically last 15–30 minutes, depending on participant needs. All steps will be taken to minimize coercion or undue influence, including emphasizing the voluntary nature of participation, the right to withdraw at any time, and that clinical care will not be affected by their decision. Voluntary participation will be reinforced throughout the study, and participants/parents will be reminded at each contact that they may withdraw at any time without penalty.

Privacy and confidentiality:

All participant information will be handled in accordance with Nemours privacy, HIPAA, and research data-security policies. Only health information necessary for the study will be accessed, including basic demographic data, history and physical information, and questionnaire responses; no genetic data, laboratory results, imaging, or surgical reports will be collected for research. Parental permission includes HIPAA Authorization for use of Protected Health Information (PHI). All study data will be coded using unique study IDs, and the linkage file connecting IDs to participant identities will be stored separately on a secure, password-protected drive accessible only to essential study personnel. Research data will be entered and stored in

encrypted REDCap databases with role-based access restrictions; any paper logs (e.g., recruitment or attendance sheets) will be kept in locked storage within restricted-access research offices. Data analyses will be conducted using de-identified datasets, and results will be reported in aggregate without individual identifiers. Quality control procedures will include fidelity checklists, routine assessments of instrument completeness, periodic audits of REDCap exports, and documentation of any deviations. After study completion, the de-identified analytic dataset will be retained per institutional policy; the linkage file will be destroyed after final reporting, and regulatory/incident logs will be archived according to required retention schedules.

Risk/Benefit:

Risk to participants:

Foreseeable risks: Physical: Minor contact injuries, allergy reactions, slips/trips in outdoor space (rare). Psychological: Emotional discomfort while answering survey items (rare). Privacy: Loss of confidentiality (unlikely; mitigated via secure systems and limited access).

Unforeseeable risks. None beyond typical outdoor animal-assisted programming.

Risks to others (bystanders/parents). Minimal; parents remain in controlled areas with a safety briefing.

Risk minimization. Screening; ESMHL supervision; infection-control standards; defined stopping rules; incident documentation; option to opt-out of any procedure or survey item.

Investigator's risk assessment. Minimal risk (commensurate with risks a healthy child might encounter in daily life or during a routine physical exam).

Benefits to Participants

Participants may experience direct benefits from participation, including increased confidence and self-efficacy in diabetes self-care, improved coping and advocacy skills, and renewed engagement in routine diabetes care. These potential benefits cannot be guaranteed; there is the potential families will experience no direct benefit.

There is potential societal benefit, as this study may generate early evidence to inform scalable, patient-centered models of diabetes education and support for youth and families.

Study Timeline:

Because enrollment is ongoing and DEEP sessions are offered seasonally (September–May), study activities occur in overlapping cycles rather than in fixed blocks. The stages below reflect the general sequence for each participant:

- Stage 1: Ongoing Screening and Enrollment
Continuous EHR-based identification of eligible youth, outreach, eligibility confirmation, and completion of parental permission and youth assent.
- Stage 2: Program Participation (September–May annually)
Enrolled participants complete four age-tailored DEEP sessions (20–30 minutes each), delivered approximately monthly or every other month within the active program season.
- Stage 3: Data Collection (Baseline → Post-Program → Follow-up)
Baseline questionnaire measures collected at enrollment; post-program measures and satisfaction surveys collected after the fourth session; routine clinical outcomes (visit attendance, A1C/TIR when available, technology uptake) abstracted up to 6 months after the participant's final session.
- Stage 4: Ongoing Data Analysis and Reporting

Data are analyzed using de-identified datasets on a rolling basis as participants complete follow-up. Final analyses, internal summaries, and dissemination (e.g., presentations, manuscripts) occur after the full cohort completes follow-up.

Data Safety Monitoring:

Because this is a minimal-risk behavioral/educational study with no investigational drugs, devices, or medical procedures, a formal Data Safety Monitoring Board (DSMB) is not required. The Principal Investigator (PI) and Co-Investigators will provide ongoing oversight of participant safety, protocol adherence, and data integrity. Study staff will document any protocol deviations, unanticipated problems, or adverse events (should any occur) and will report them to the PI immediately and to the IRB per institutional reporting requirements. Data quality and completeness will be monitored through routine REDCap audits, fidelity checklists, and verification of questionnaire and follow-up data. All study data will be stored on encrypted platforms with role-based access controls. The PI will review safety and data quality indicators at regular team meetings and will implement corrective actions as needed to ensure the continued protection of participants.

Conflict of Interest:

Dr. Patton serves on a clinical advisory board for Glooko, Inc., a diabetes data-aggregation company. This advisory role is unrelated to the current study. The protocol does not use Glooko products or services; all study data are obtained directly from the electronic health record and study questionnaires, with no involvement from Glooko or any external vendor. This relationship has been disclosed to the Committee for Research Integrity, and any potential conflicts will be managed in accordance with Nemours policies and guidance.

Publication and Presentation Plans:

Findings from this study will be disseminated following completion of data collection and analysis. The Principal Investigator plans to present preliminary results at the 2027 International Society for Pediatric and Adolescent Diabetes (ISPAD) annual meeting. Manuscripts based on de-identified, aggregate data may be submitted to peer-reviewed journals in pediatric diabetes, behavioral health, or healthcare delivery science. All presentations and publications will follow Nemours policies on authorship, confidentiality, and protection of participant privacy. No identifiable information will be included in any dissemination materials.

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