

Evaluating Long-term Use of a Pediatric Robotic Exoskeleton (P.REX/Agilik) to Improve Gait in Children With Movement Disorders

NCT05726591

Status	RECRUITING
Phase	Not Applicable
Sponsor	National Institutes of Health Clinical Center (CC)
Enrollment	44 participants

Key Eligibility Criteria

Inclusion (9)

- In order to be eligible to participate in this study, an individual must meet all of the following criteria:
 - Provision of signed and dated separate informed consent and assent forms for screening purposes. Upon inclusion in the protocol, provision of signed and dated informed consent and assent forms to begin participation in the study will be necessary.
 - Stated willingness to comply with all study procedures and availability for the duration of the study, or alternatively, ability to do so based on parent report and physician observation during history and physical examination.
 - Age 3 to 17 years old.
 - Have a gait pathology involving the knee joint, from a diagnosis of cerebral palsy, muscular dystrophy, spina bifida, or incomplete spinal cord injury.
- ... and 4 more (see full listing online)

Exclusion (5)

- An individual who meets any of the following criteria will be excluded from participation in this study:
- Any neurological, musculoskeletal or cardiorespiratory injury, health condition, or diagnosis other than cerebral palsy, muscular dystrophy, spina bifida, or incomplete spinal cord injury that would affect the ability to walk as directed with the robotic exoskeleton.
- A history of uncontrolled seizure in the past year.
- Pregnancy. A urine test will be performed for all participants who are able to become pregnant at the initial screening visit and in the case of a positive test, the participant will be excluded from participation. Further monitoring will rely on self-reporting of interruption in menstruation that would require re-testing for pregnancy at the next visit.
- Any acute cardiopulmonary condition which limits exercise to less than 60 minutes per session or less than 5 days per week.

Locations (1 total)

National Institutes of Health Clinical Center, Bethesda, Maryland, United States