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Home-Based Versus Laboratory-Based Robotic Ankle Training for Children With Cerebral Palsy: A Pilot Randomized Comparative Trial



Kai Chen, PhD,^{a,b} Yi-Ning Wu, PhD,^c Yupeng Ren, MS,^a Lin Liu, MS,^{a,d} Deborah Gaebler-Spira, MD,^{a,b} Kelly Tankard, BA,^{a,e} Julia Lee, PhD,^b Weiqun Song, MD,^d Maobin Wang, MD,^d Li-Qun Zhang, PhD^{a,b}

From the ^aRehabilitation Institute of Chicago, Chicago, Illinois; ^bNorthwestern University, Chicago, Illinois; ^cUniversity of Massachusetts Lowell, Lowell, Massachusetts; ^dXuanwu Hospital, Beijing, China; and ^eUniversity of Kansas School of Medicine, Kansas City, Kansas.

Abstract

Objective: To examine the outcomes of home-based robot-guided therapy and compare it to laboratory-based robot-guided therapy for the treatment of impaired ankles in children with cerebral palsy.

Design: A randomized comparative trial design comparing a home-based training group and a laboratory-based training group. **Setting:** Home versus laboratory within a research hospital.

Participants: Children (N=41) with cerebral palsy who were at Gross Motor Function Classification System level I, II, or III were randomly assigned to 2 groups. Children in home-based and laboratory-based groups were 8.7 ± 2.8 (n=23) and 10.7 ± 6.0 (n=18) years old, respectively. **Interventions:** Six-week combined passive stretching and active movement intervention of impaired ankle in a laboratory or home environment using a portable rehabilitation robot.

Main Outcome Measures: Active dorsiflexion range of motion (as the primary outcome), mobility (6-minute walk test and timed Up and Go test), balance (Pediatric Balance Scale), Selective Motor Control Assessment of the Lower Extremity, Modified Ashworth Scale (MAS) for spasticity, passive range of motion (PROM), strength, and joint stiffness.

Results: Significant improvements were found for the home-based group in all biomechanical outcome measures except for PROM and all clinical outcome measures except the MAS. The laboratory-based group also showed significant improvements in all the biomechanical outcome measures and all clinical outcome measures except the MAS. There were no significant differences in the outcome measures between the 2 groups.

Conclusions: These findings suggest that the translation of repetitive, goal-directed, biofeedback training through motivating games from the laboratory to the home environment is feasible. The benefits of home-based robot-guided therapy were similar to those of laboratory-based robot-guided therapy. Archives of Physical Medicine and Rehabilitation 2016;97:1237-43

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Cerebral palsy (CP) is the leading cause of childhood motor disability and is caused by a nonprogressive lesion to an immature brain.¹ Most children with CP have gait deviations; \sim 70% of them are able to walk, either with or without assistive devices.^{2,3} Gait

Clinical Trial Registration No.: NCT02359799.

deviations seen in children with CP lead to higher energy expenditure⁴ and affect their quality of life.⁵ Some children with CP might even lose gait function in adolescence and adulthood, which affects their long-term independence.^{6,7} More than half of the gait deviations in children with CP involve the ankle joint, including foot drop, toe walking, and equinus.⁸ Spasticity, contracture, and/or muscle weakness is widely thought to cause poor ankle motor control in children with CP.^{9,10} Recently, Willerslev-Olsen et al¹¹ proposed that altered central drive and increased passive muscle stiffness, rather than exaggerated stretch reflex (spasticity), are the main causes of foot drop and toe walking in children with CP.

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Although spasticity might not directly cause foot drop or toe walking, over time it could cause muscle property changes, including increased muscle stiffness,¹² that can contribute to gait deviations. With improvement in ankle control, reduction of spasticity and excessive stiffness should therefore enhance gait efficiency in children with CP.^{10,11,13}

When it comes to appropriate interventions to improve ankle functions, targeted tone management and exercise strategies are equally critical.¹⁴ Although stretching has long been used in rehabilitative programs to prevent or manage contracture and spasticity, recent system reviews report a lack of evidence supporting the benefit of stretching used in isolation.^{15,16} However, to abandon stretching in pediatric rehabilitation would be imprudent before more in-depth investigation.¹⁷ Previous and more recent research by means of biomechanical approaches and/or ultrasound methodology demonstrate changes in muscle properties, such as increased muscle length, decreased muscle stiffness, and altered muscle-tendon compliance, after acute stretching¹⁸⁻²¹ as well as after a period of stretching as a part of therapy.²² Freitas and colleagues^{23,24} capitalized on an advanced experimental setup to demonstrate muscle and joint responses to varied intensity and duration of stretch. Their observations further support the important role of stretching with appropriate intensity and duration in modulating muscle properties by initiating the muscle and joint adaptation and preconditioning muscles for later treatment, such as with active movement training. Developing strategies to integrate treatment with fun, active movement is important.²⁵ Neuroplasticity is important for motor recovery and development, and it is induced in response to active, repetitive, and intense practice of activities that the individual is motivated to learn.^{26,27} Therefore, to facilitate neuroplasticity, high-intensity exercise should be achieved, although the optimal dose is still unclear. Nonetheless, limited clinical visits are not capable of neuroplastic training, regardless of the optimal dose.

Although therapeutic interventions such as stretching and active movement training differ, both approaches have the same treatment goal of enhancing ankle function and thereby improving gait in children with CP. Both interventions also face the same barrier of insufficient dose of therapy during limited clinical visits. Home programs have the potential of increasing access to therapy. Pediatric home programs involve both a child and a parent/caregiver(s) in their home environment to maximize the potential of a child to reach the expected outcomes through regular practice.²⁸ Although home training may increase the dose of treatment, the current form of home programs is less controllable.²⁹ A robot can be programmed to perform tasks in a consistent manner according to human commands. Emerging robot-guided therapy demonstrates its potential to deploy active movement training, which further improves clinical outcome measures.³⁰⁻³⁶ Using a robot for home treatment might create an additional therapeutic regimen for potential spasticity reduction and better motor control in a repeated and controllable

List of abbreviations:	
6MWT	6-minute walk test
AROM	active range of motion
СР	cerebral palsy
GMFCS	Gross Motor Function Classification System
PBS	Pediatric Balance Scale
PROM	passive range of motion
SCALE	Selective Control Assessment of the Lower Extremity
TUG	timed Up and Go

manner. However, there has been no literature support for homebased therapy for ankle rehabilitation of children with CP.

Previous studies have shown that combined passive and active training using a portable robot for children with CP is effective and feasible in a research laboratory³⁵ and in a clinical setting.³³ However, there is a gap in our understanding of the feasibility and efficacy of robot-guided therapy in the home environment where there is limited professional supervision. Home therapy has a potential to increase convenient access to individualized patientcentered rehabilitation programs. There could be many reasons for the reduced translation of robot-guided therapy programs from the laboratory to a home environment including safety concerns, prohibitive cost of devices, and user's hesitation about the complexity of a robot. In this study, we aimed to evaluate the effectiveness of a home program, which included both passive and active movement training using a portable robot for children with CP. To better demonstrate the potential of the home program to provide convenient access to rehabilitation, in this randomized controlled trial, we examined differences by comparing homebased therapy with the same therapy protocol conducted in the well-controlled environment of a research laboratory setting for a similar cohort of children with CP.

Methods

Participants

Forty-one children with CP who have reduced active or passive range of motion (AROM, PROM) and spasticity of the ankle were recruited in the 6-week intervention by the pediatric physiatrist in the Rehabilitation Institute of Chicago. The recruited participants were assigned to laboratory-based or home-based group using a randomly generated number sequence. The laboratory-based group was compared to the home-based group. Figure 1 shows the CONsolidated Standards Of Reporting Trials enrollment flowchart. Table 1 presents the demographic data of the participants. The sample size was determined by a power analysis on the basis of expected pre- to postintervention changes, and the mean improvement in joint AROM was estimated to be $7^{\circ}\pm5^{\circ}$. At a significance level of $\alpha = .05$, 24 participants were needed per group to achieve a power of 94% to detect within-group changes (ie, pre- to postintervention changes). Because of the pilot and exploratory nature of the study, the sample size was not based on the ability to detect between-group differences.

Inclusion criteria were (1) individuals who were at Gross Motor Function Classification System (GMFCS) levels I to III (able to walk with or without any assistive device); (2) individuals aged between 7 and 18 years; and (3) individuals who could follow instructions and express any discomfort during the sessions. Exclusion criteria were (1) individuals who received surgery, serial casting, or botulinum toxin type A injection in the 6month period before recruitment; (2) individuals who had ankle contracture; or (3) individuals could not sit for 1 hour. The study was approved by the Institutional Review Board of Northwestern University. All participants and/or parents gave informed consent at the beginning of the research study.

Intervention

A 6-week combined passive stretching and active movement intervention of 1 ankle joint using a portable rehabilitation robot Download English Version:

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