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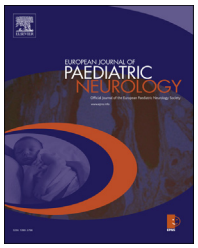

Original article

Prospective controlled cohort study to evaluate changes of function, activity and participation in patients with bilateral spastic cerebral palsy after Robot-enhanced repetitive treadmill therapy

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ABSTRACT

Background: Robot-enhanced therapies are increasingly being used to improve gross motor performance in patients with cerebral palsy.
Aim: To evaluate gross motor function, activity and participation in patients with bilateral spastic cerebral palsy (BS-CP) after Robot-enhanced repetitive treadmill therapy (ROBERT) in a prospective, controlled cohort study.
Methods: Participants trained for 30–60 min in each of 12 sessions within a three-week-period. Changes in Gross Motor Function Measure (GMFM 66) scores, standardized walking distance, self-selected and maximum walking speed (ICF domain "Activity"), and Canadian Occupational Performance Measure (COPM; "Participation") were measured. Outcome measures were assessed three weeks in advance (V1), the day before (V2) as well as the day after, and 8 weeks after ROBERT (V3 + V4).
Results: 18 patients with BS-CP participated; age 11.5 (mean, range: 5.0–21.8) years, body weight 36.4 (15.0–72.0) kg. GMFCS levels I–IV were: $n = 4$; 5; 8; 1. There was no significant difference comparing V1 and V2. GMFM 66 (total +2.5 points, Dimension D +3.8 and E +3.2) and COPM (Performance +2.1 points, Satisfaction +1.8 points) showed statistically significant improvements for V3 or V4 compared to V1 or V2 representing clinically meaningful effect sizes. Age, GMFCS level, and repeated ROBERT blocks correlated negatively with GMFM improvement, but not with COPM improvement.
Interpretation: Following ROBERT, this prospective controlled cohort study showed significant and clinically meaningful improvements of function in ICF domains of "activity" and

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"participation" in patients with BS-CP. Further assessment in a larger cohort is necessary to allow more specific definition of factors that influence responsiveness to ROBERT program.

1. Introduction

Cerebral palsy (CP) is the most common cause of impairment in gross motor function in childhood, and a multidisciplinary therapy approach represents the gold standard of care.[1] The strain to develop adequate functional therapies addressing all different domains of the World Health Organisation – International Classification of Functioning, Disability and Health, Children & Youth version (WHO ICF-CY 2005)[2] is increasing in order to postpone or prevent secondary musculoskeletal alterations and to improve function, activity, and participation of the patients. Incidence and severity of motor impairment in BS-CP has declined during the last two decades,[3] but bilateral spastic CP (BS-CP) still represents the largest subtype of CP comprising approximately 50% of the affected patients.[4]

Task specific therapies focusing on body weight-supported treadmill training for children with BS-CP have shown improvements of endurance and gait velocity,[5] in stepping kinematics,[6] as well as gross motor function.[7] Compared to strengthening programs, home-based supported speed treadmill training was not superior in respect to gain of participation, individual goals, and satisfaction.[8] Yet, knowledge about the effects in children within the first years of motor development is still limited.[9]

Robot-enhanced therapy devices (e.g. the Lokomat®, Hocoma, Volketswil, Switzerland, or Gait Trainer GT 1®, Reha Stim, Berlin, Germany, and others) help to increase treatment intensity of task specific gait training and they allow quantifying the exact amount of therapy performed (walking distance, walking duration, walking speed, etc.). A paediatric version of the Lokomat® is adapted to children from the age of 4 years onward (femur length 210–350 mm).[10,11] Robot-enhanced repetitive treadmill therapy has proven to be well tolerated[12] and uncontrolled studies have shown significant improvements of function and activity in children with CP, which could be maintained over a period of more than six months.[13–15] For the Gait Trainer GT 1 one randomized controlled trial recently showed improvements in gait velocity, endurance, spatiotemporal, and kinematic gait parameters in patients with cerebral palsy,[16] but outcome measures did not include ICF domain of participation.

The superiority of Robot-enhanced step training and treadmill therapy has recently been questioned and proclaimed to be an expensive workhorse that can be further tested, but probably will never grow into the crowned thoroughbred as expected, especially in adult rehabilitation.[17] In contrast to adult rehabilitation, in patients with CP motor development is primarily affected, making Robot-enhanced treadmill therapy still a promising tool to induce prolonged training duration with high repetitions of steps, while inducing a reproducible, kinematically consistent, symmetrical gait pattern to a locomotion-learning and highly adaptive central nervous system. A recent overview on paediatric treadmill training reviews summarized encouraging results, but more rigorous research was requested before effectiveness could be proven and clinical guidelines could be developed.[18]

The aim of this study was to assess ICF domains of "body function", "activity" and "participation" in a phenotypically and aetiologically well-defined cohort of patients with bilateral spastic cerebral palsy undergoing an intensified Robot-enhanced repetitive treadmill therapy (ROBERT program) with a focus on clinically meaningful improvements and to accentuate further research questions from a clinical perspective.

2. Materials and methods

2.1. *Participants*

To assure the diagnosis of BS-CP a phenotypically homogeneous cohort (clinical picture of bilateral spastic CP as defined by the SCPE)[19] was matched with morphology (periventricular lesions: periventricular leucomalacia or periventricular white matter haemorrhage) reported by cranial MRI or post-natal transfontanellar ultrasound and aetiology (weeks of gestation). Children with BS-CP were treated in an outpatient setting at the Department of Paediatric Neurology and Developmental Medicine, Hauner Children's Hospital, University of Munich, Germany. Patients who received their first therapy block, but also patients who returned for a second to fifth ROBERT block were included. The local ethics committee gave ethical approval for this study.

2.2. *Therapy device*

Robot-enhanced repetitive treadmill therapy (ROBERT program) was conducted using the commercially available (Paediatric) Lokomat® (Hocoma Inc., Volketswil, Switzerland). The Lokomat® consists of two exoskeletons, which are adjustable to the anthropometrics of the patient. Several braces allow joining the patient with the exoskeleton. The exoskeleton is connected to the frame of a body weight support system, which provides vertical stability. For body weight support, a counter system with a harness is used. Foot lifting belts passively position the ankle joints. For patients with femur length of 210–350 mm the paediatric exoskeleton can be used, longer femoral length requires the adult exoskeleton. Several security measures on the patient's and the therapist's side provide safe training conditions. Body weight support, step length, guidance force of the exoskeleton, as well as walking speed can be adjusted via personal computer interface using the Lokocontrol® software (Hocoma Inc., Volketswil, Switzerland).