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Protocol of robot-assisted gait training in children with cerebral palsy

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Background
Mobility and walking ability are the most important areas of rehabilitation in children with cerebral palsy. Therefore, many rehabilitative interventions focus on walking ability. Partial weight support gait training is known to be effective therapy. Likewise, robot-assisted gait training enables children to have effective gait training as it partially supports the body weight and to walk longer. Robot-assisted gait training is established as treatment option, but the clinical evidence on the neurologic recovery or musculoskeletal system is rare. So, in this study, we will assess the impact of robot-assisted gait training on neurologic recovery, cardiopulmonary function, and body composition in children with cerebral palsy by comparing functional change of usual care period and robotic therapy period.

Methods/Design
The study design is single-blinded, pragmatic, randomized, cross-over trial. Children with cerebral palsy will be recruited and randomized into two groups ; Group 1 (Robotic Training – Usual Care), Group 2 (Usual Care – Robotic training-Usual Care). Each period is 6 week. The patient will receive robotic therapy 3 days per week for 6 weeks in robotic training period in addition to the usual care. The inclusion criteria are like as follow; Children (1) diagnosed with spastic cerebral palsy(3~12 years-old); (2) gross motor function classification system Level II~IV ; (3) height of 98 ~ 160 centimeter ; (4) follow the instructions and communicate if they feel pain or discomfort (weeFIM score: more than 11 points in communication, social cognition domain); We excluded patients with any of the following ; (1) cognitive impairment so that each assessment can not be performed properly ; (2) history of neurosurgery or orthopedic surgery operated on limbs ; (3) severe joint contracture (knee joint : more than 20 degrees flexion contracture, hip joint more than 40 degree contracture). We will measure gross motor function measure (GMFM), functional independence measure (WeeFIM), manual muscle test (MMT), range of motion (ROM), modified ashworth scale (MAS) before and after each treatment periods. The motor evoked potential, balance test, cardiopulmonary exercise test, body composition analysis will be assessed before and after robotic therapy period. Treatment effects and follow up effects will be analyzed. Discussion: This study would provide an important evidence on impact of robot-assisted gait training not only on the neurologic recovery but also on cardiopulmonary function, and body composition in children with cerebral palsy.

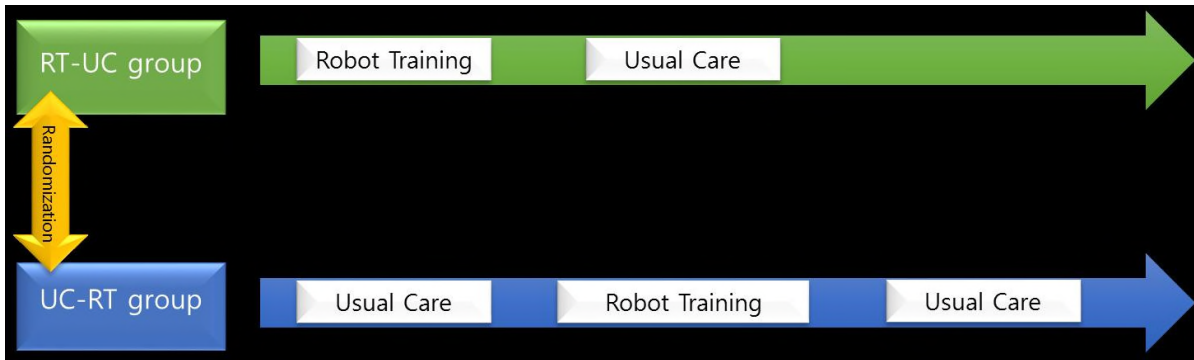| Assessment	Assessment 1		Assessment 2		Assessment 3		Assessment 4	
	RT-UC	UT-RT	RT-UC	UT-RT	RT-UC	UT-RT	RT-UC	UT-RT
GMFM, C, D, E (dimension)	○	○	○	○	○	○		○
MMT	○	○	○	○	○	○		○
Modified Ashworth scale	○	○	○	○	○	○		○
Balance test	○		○	○		○		
Gait analysis	○		○	○		○		
MEP	○		○	○		○		
Body composition analysis	○		○	○		○		
CPET	○		○	○		○		
COPM	○	○	○	○	○	○		○

Table 1. Assessment Protocol

Fig 1. Study protocol of 2 groups