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Wearable interactive lower-limb exoskeleton robotic device for gait training of post-stroke patients on different walking conditions

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Introduction

Stroke is the major cause of adult disability worldwide. Over half of the post stroke survivors have residual neurological deficit, most commonly hemiplegia or loss of motor control, which result in impaired mobility and inability of self-care. After stroke, foot drop and inadequate knee control during the swing phase in gait cycle often result in poor compensatory gait pattern and fall. Therefore, effective gait recovery is essential to improve life independency of stroke survivors. An interactive lower limb exoskeleton robotic device was designed by Department of Bioengineering of The Chinese University of Hong Kong aiming to facilitate gait training, particularly level ground walking and stair climbing, in stroke rehabilitation.

Objectives

-To evaluate the performance of exoskeleton robotic as a gait trainer in subacute phase of stroke. -To investigate the effectiveness of exoskeleton robotic as a gait trainer compared to conventional rehabilitation methods.

Methodology

This is a randomized controlled trial which has been started at Shatin Hospital since July 2017. With collaboration from division of Neurology and Physiotherapy, 32 patients with ischaemic or haemorrhagic stroke will be recruited into this study. The inclusion criteria are patients who are able to follow simple commands and walk for 6 meters with one personal assistant, with or without walking aids. Participants will be excluded if they have any additional medical or psychological dysfunctions affecting gait training. Enrolled patients will be randomized into four groups: (1) Ankle Robotic Gait Training (Ankle Robot) Group, (2) Ankle Sham Group, (3) Knee Robotic Gait Training (Knee Robot) Group, and (4) Knee Sham Group. Each participant will receive 30-minute gait training sessions, 3-5 times per week for 20 sessions. For the Robotic group, subjects will wear the exoskeleton robotic leg on the affected side during the gait training sessions; while the control group will follow the same procedure though without the active assistance from exoskeleton robot. Physiotherapist will supervise the gait pattern of subjects and advise on the movement pattern of robotic device. Clinical assessments will evaluate the training effects of both groups by comparing the results of the pre and post assessments, and the 3-month and 6-month follow up. Subjects will be assessed using the following tests: 6-minute walking test (6MWT), Berg Balance Scales (BBS), Fugl-Meyer Assessment for lower extremity, the Modified Ashworth Scale, the Lower Extremity Functional Scale, and the Functional Ambulatory Category (FAC).

Result

Here we present the preliminary results of first 8 subjects enrolled into the study – 6 patients (5 ankle group & 1 knee group) completed 20 training sessions, while 2 patients are still receiving on-going training. The male to female ratio was 1:1. The mean age was 70.4±9.6 years old. The ratio left to right limb involvement was 2:1. The trainings were well tolerated. No adverse events were reported. Significant improvements were observed in FAC (Z=-2.07;p=o.038), BBS (Z=-2.02, p=0.043), 6MWT (Z=-2.02, p=0.043) and 10MWT (Z=-2.02, p=0.043). The results suggested improvements in terms of balance, gait stability and endurance in walking. Conclusion: The exoskeleton robotic gait training can safely provide high-intensity and high-dosage training to patients in the subacute phase of stroke. Our preliminary results provide positive findings for the application of robotic therapy on the gait and stair training. Further study with large sample size is needed to further determine its efficacy in patients with different degree of disabilities.