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The Effect of Robot-Assisted Gait Training in Patients With Parkinson's Disease : Study Protocol

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Background/Objective
Loss of dopamine in the sensorimotor territories of basal ganglia disturb habitual control in Parkinson's disease (PD). Consequently, patients have to make a cognitive effort to perform habitual action such as gait. In other words, gait automaticity is reduced. Robot-assisted gait training (RAGT) had been developed to restore gait function by promoting neuroplasticity through repetitive locomotor training and utilized in gait training for stroke patients. However, contradictory Results have been reported for PD patients. In addition, mechanism of RAGT's treatment effect is still unknown. The aim of this study is to investigate the effect of RAGT and to unveil the mechanism of treatment effect by comparing the change in gait automaticity and functional connectivity in patients with PD.

Methods
This is a prospective, single-blind, single-center, randomized controlled trial. Eligible participants will be randomly allocated to: 1) the robot-assisted gait training with Walkbot-S™ (P&S Mechanics, Seoul, Korea) group, or 2) the treadmill training group. Participants will receive 45-minutes of each intervention for 3 times per week for 4 weeks. The gait speed during RAGT will be targeted to the maximum speed depending on the participant's height and the same principle will be applied to the treadmill training group to match the training intensity. The primary outcome measure is the gait speed measured by 10-Meter Walk Test at a comfortable pace under single-task. Secondary outcomes include dual-task interference, Berg Balance Scale, Timed Up and Go test, Korean version of the Falls Efficacy Scale-International, New Freezing of Gait Questionnaire, MDS-UPDRS, and functional connectivity measured by resting-state functional MRI. Dual-task interference, an indicator of gait automaticity, is defined by the difference between dual-task and single-task performance. Baseline assessments (T0) will be conducted to acquire clinical characteristics and values of primary and secondary outcome measures before the intervention. Post-intervention assessments (T1) to compare the short-term efficacy of each intervention will be performed within three days after the intervention. Follow up assessments (T2) to detect potential long-term effects will be conducted one month after the intervention.

Discussions
This study will reveal the effect of RAGT using exoskeletal robot, not only on gait speed, but also on gait automaticity, balance function, fall risk, quality of life, and disease

disability. Besides, the study's findings will shed new light on the mechanism of RAGT effect such as the change in gait automaticity and brain functional networks, following the RAGT. We hope that the information acquired from this trial will influence the clinical decision when physiatrists plan gait training for PD patients.

Trial status:

The study has been initiated in May 2018 and will be completed in Dec 2019. (ClinicalTrials.gov: NCT0349057)

Table 1. Schedule for outcome measures per visit

	Baseline assessment (T0)	Post-intervention (T1)	1-month follow up (T2)
Demographics	√		
10MWT (single-task)	√	√	√
10MWT (dual-task)	√	√	√
BBS	√	√	√
TUG	√	√	√
KFES-I	√	√	√
NFOG-Q	√	√	√
MDS-UPDRS	√	√	√
rs-fMRI	√	√	

10MWT, 10-Meter Walk Test; BBS, Berg Balance Scale; TUG, Timed Up and Go Test; KFES-I, Korean version of the Falls Efficacy Scale-International; FOG-Q, New Freezing of Gait Questionnaire; MDS-UPDRS, Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale; rs-fMRI, resting-state functional MRI.

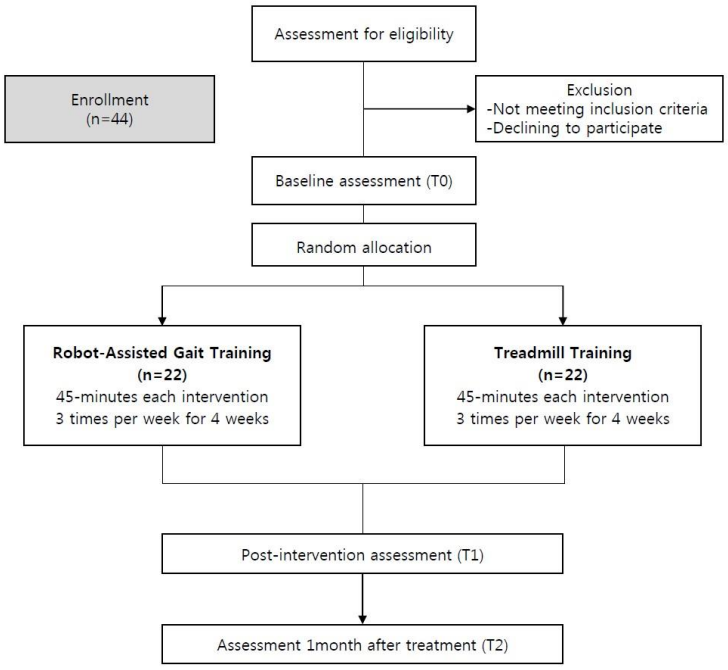

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram