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Candidates for Robot-assisted Gait Training with a Wearable Exoskeleton in Subacute Stroke Patients

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Introduction

- The overground robot-assisted gait training (RAGT) has been documented to have a positive impact on the recovery of ambulatory function in patients with subacute stroke.
- In this analysis, we investigated the characteristics of patients with subacute stroke for the appropriate indications for an exoskeleton in patients with subacute stroke through this prespecified analysis.
- The identification of the appropriate indication of RAGT with an exoskeleton will aid in the design of individual treatment plans and the accurate stratification of patients for better outcomes after RAGT in patients with subacute stroke.

Materials and Methods

▪Study Design

- This study was a prespecified analysis of data from a previous international, multicenter, randomized, controlled trial of RAGT utilizing an exoskeleton (ANGEL LEGS M20, Angel Robotics, Co., Ltd.) compared with the conventional gait training in subacute stroke patients (Fig. 1.).

International, Multi-center, Randomized Controlled Trial

- Participating Institutes
  - Malaysia
    - Daehan Rehabilitation Hospital Putrajaya,Malaysia
  - Republic of Korea
    - Severance hospital
    - National Traffic Injury Rehabilitation Hospital
    - Samsung Medical Center
    - National Health Insurance Service Ilasn Hospital
- Clinical Trial
  - Randomized Controlled Trial
- Participants: 151 subacute stroke patients

The trial is registered on clinicaltrials.gov (NCT05157347) and CRIS (KCT0006815).

Figure. 1. International, Multi-center, Randomized Controlled Trial

- Each RAGT and the conventional gait training was provided five times per week for a period of four weeks (Fig. 2).

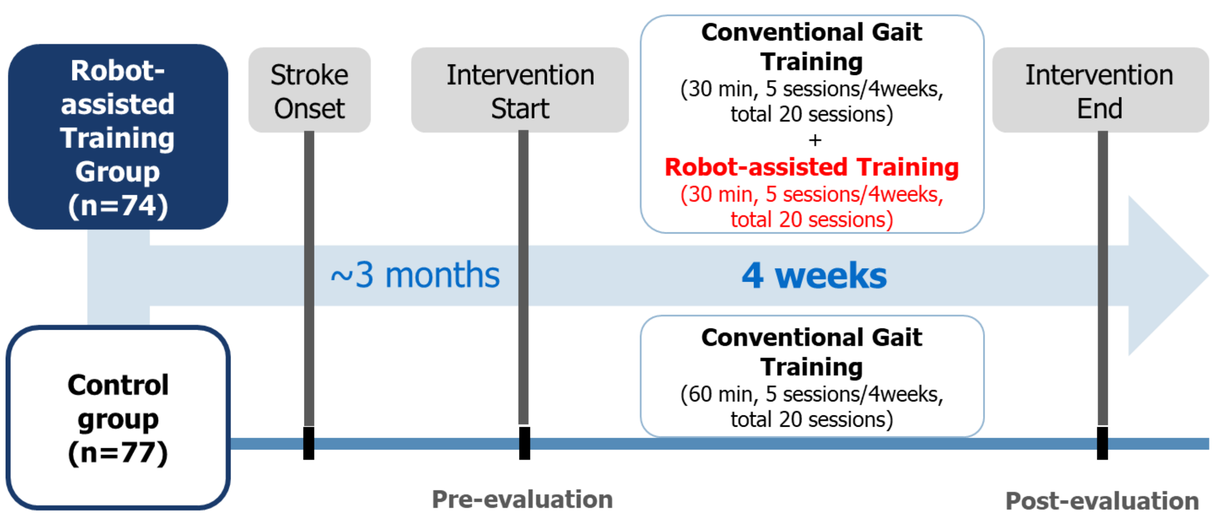

Figure 2. Study Design

- A total of 151 patients with subacute stroke were recruited. Of these, 58 participants were placed in the RAGT group and 69 in the control group were included in the final analysis (Fig.2)

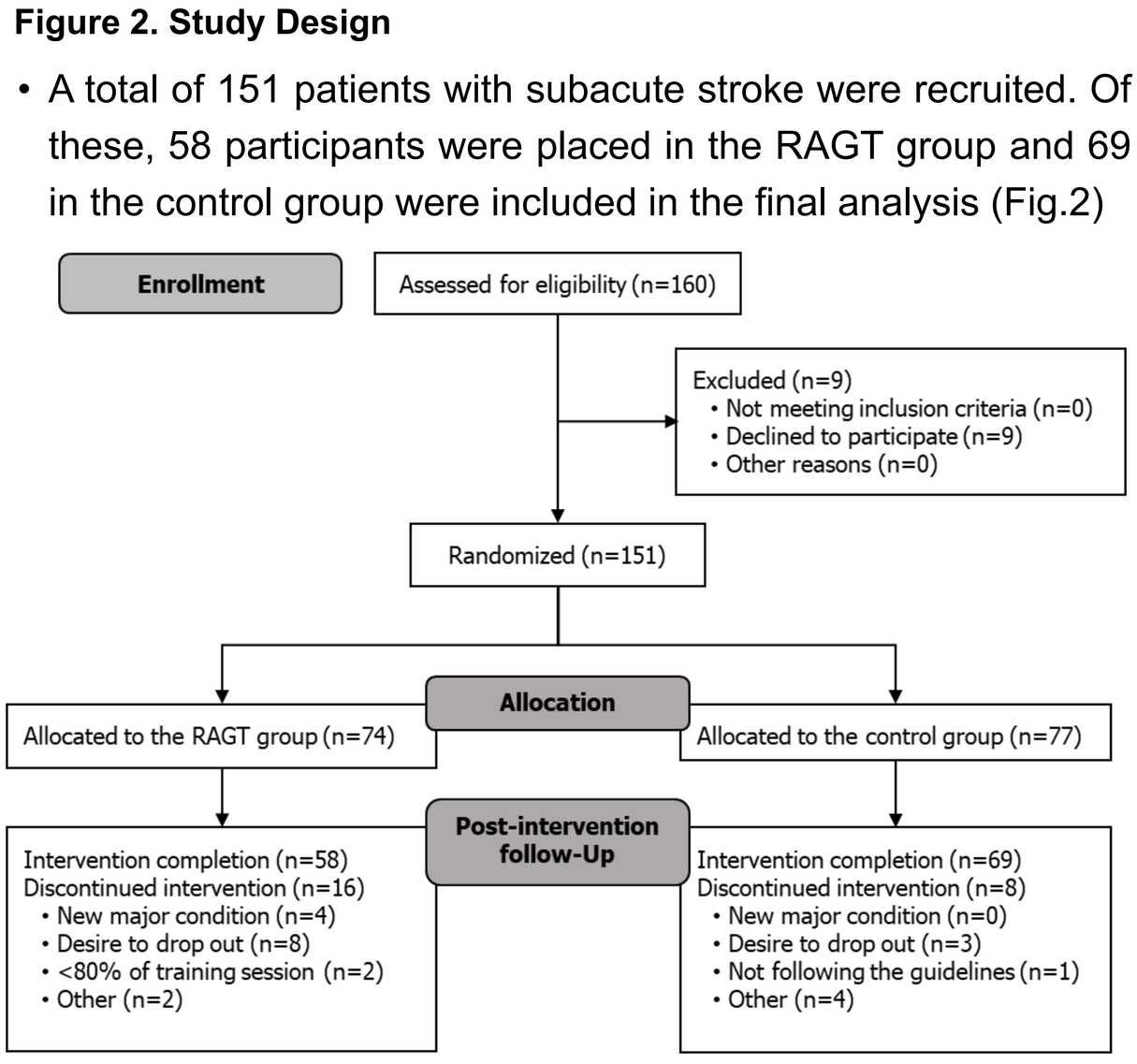

Figure 3. CONSORT Flow Diagram of the Study
RAGT, robot-assisted gait training

▪ Prespecified Analysis

- Gait function was assessed with the Functional ambulatory category (FAC) before and immediately after intervention. An FAC score of >3 immediately post-intervention was defined as the ability to ambulate independently and clinically significant.
- The potential influencing factors
  - Baseline descriptive characteristics, age, sex, body mass index (BMI), and time since stroke onset
  - FAC
  - Fugl-Meyer Assessment-Lower Extremity (FMA-LE)
  - Lower limb score of Motricity Index (MI-LL)
  - Trunk control test (TCT)
  - Berg Balance Score (BBS)
  - Geriatric Depression Scale-short form (GDS-SF)
  - EuroQol-5D (EQ-5D)
- Univariate and multivariate binary logistic regression models were used to determine possible predictors of clinically significant response to the RAGT and the conventional gait training.

Results

- Of the 58 patients in the RAGT group and 69 in the control group, 31 (53.4%) and 46 (66.7%) patients who reached to the independent gait of FAC (≥3) were classified as good responders.
- Table 1 showed the results of the univariate analysis.

Table 1. Binary logistic regression analysis

	RAGT group		Control group	
	Exp(β) (95% CI)	p value	Exp(β) (95% CI)	p value
Demographic characteristics				
Sex	-0.820 (0.149-1.300)	0.138	-0.646 (-0.236~1.771)	0.396
Age	-0.992 (0.986~1.029)	0.654	-0.965 (-0.925~1.007)	0.100
BMI	0.975 (0.826~1.152)	0.768	1.132 (0.948~1.351)	0.170
Stroke type	0.766 (-0.253~2.314)	0.636	1.697 (0.618~4.659)	0.305
Stroke duration	0.980 (0.956~1.005)	0.110	0.972 (0.949~0.996)*	0.021
Functional characteristics				
FAC	3.319 (1.218~9.045)*	0.019	2.090 (1.004~4.351)*	0.049
K-MMSE	1.168 (1.031~1.325)*	0.015	1.010 (0.931~1.095)	0.813
TCT	1.038 (1.000~1.078)	0.051	1.031 (0.995~1.068)	0.088
BBS	1.060 (0.998~1.125)	0.059	1.053 (1.003~1.106)*	0.039
FMA-LE	1.115 (1.023~1.215)*	0.014	1.089 (1.018~1.165)*	0.014
MI-LL	1.037 (1.003~1.072)*	0.030	1.044 (1.012~1.077)*	0.007
GDS-SF	1.013 (0.895~1.148)	0.837	0.924 (0.815~1.048)	0.217
EQ-5D	0.997 (0.124~8.031)	0.998	3.241 (0.476~22.087)	0.230

- The two independent factors with the greatest impact on the response to RAGT group for the achievement of independent gait were K-MMSE, and MI-LL ($p<0.05$). However, in the control group, stroke duration and Mi-LL were significant independent factors ($p<0.05$, Fig. 4).

Figure 4. Significantly independent factors to predict good responders RAGT, robot-assisted gait training

Conclusions

- This prespecified analysis suggest that the efficacy of **RAGT with a wearable exoskeleton** appears to be **less dependent on time since onset** within the subacute phase, highlighting the importance of **preserved cognitive function** for optimal outcomes.

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