



FreeD-Enabled RAGT in Incomplete SCI: An Exploratory RCT



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Background

The FreeD module of the Lokomat allows dynamic pelvic motion during robot-assisted gait training (RAGT), which may promote more physiological gait patterns and enhance neuromuscular activation. This exploratory randomized controlled trial evaluated the efficacy of FreeD-enabled RAGT in individuals with incomplete spinal cord injury (SCI) and examined whether baseline ambulatory motor capacity influenced treatment response.

Materials & Methods

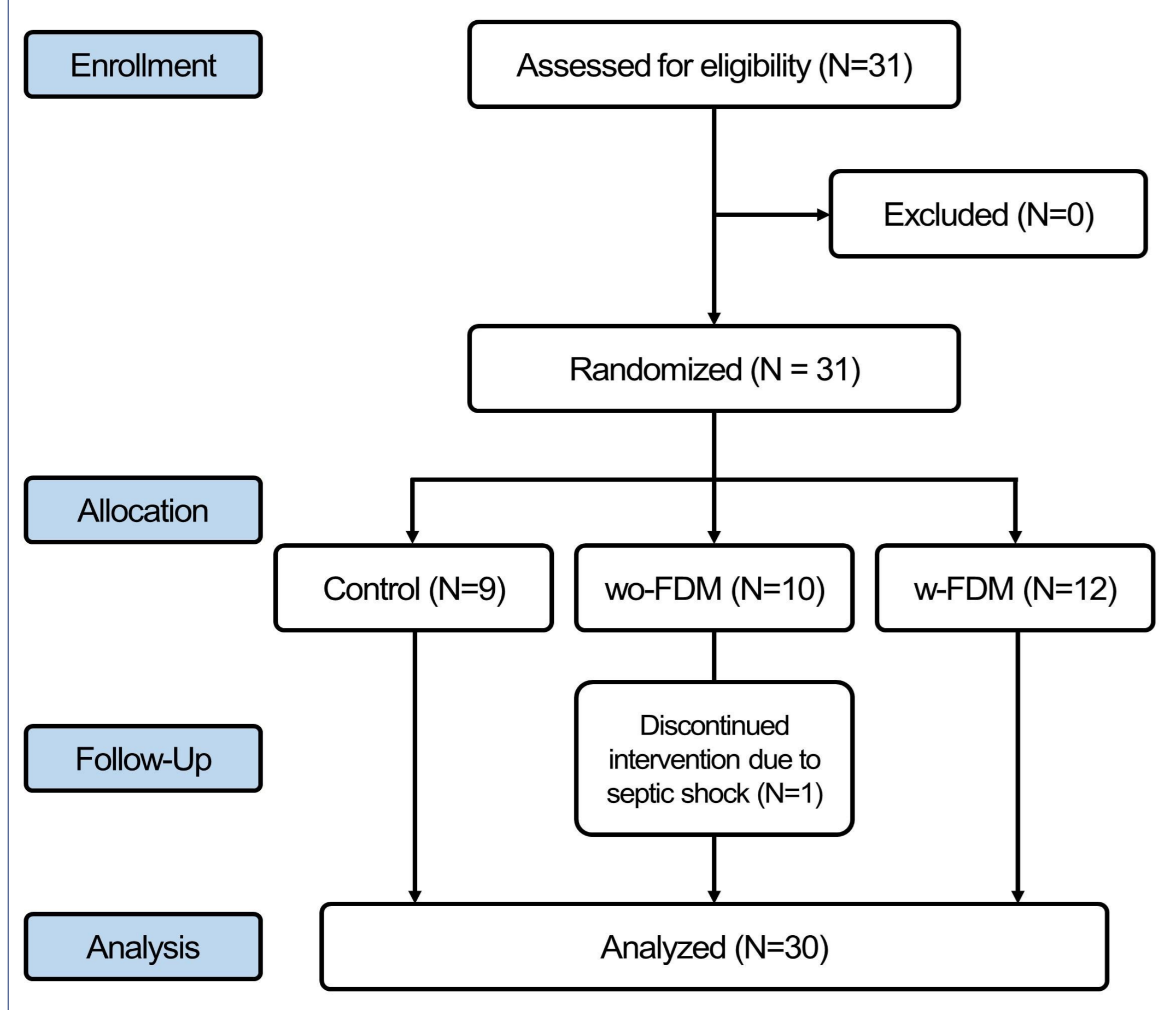
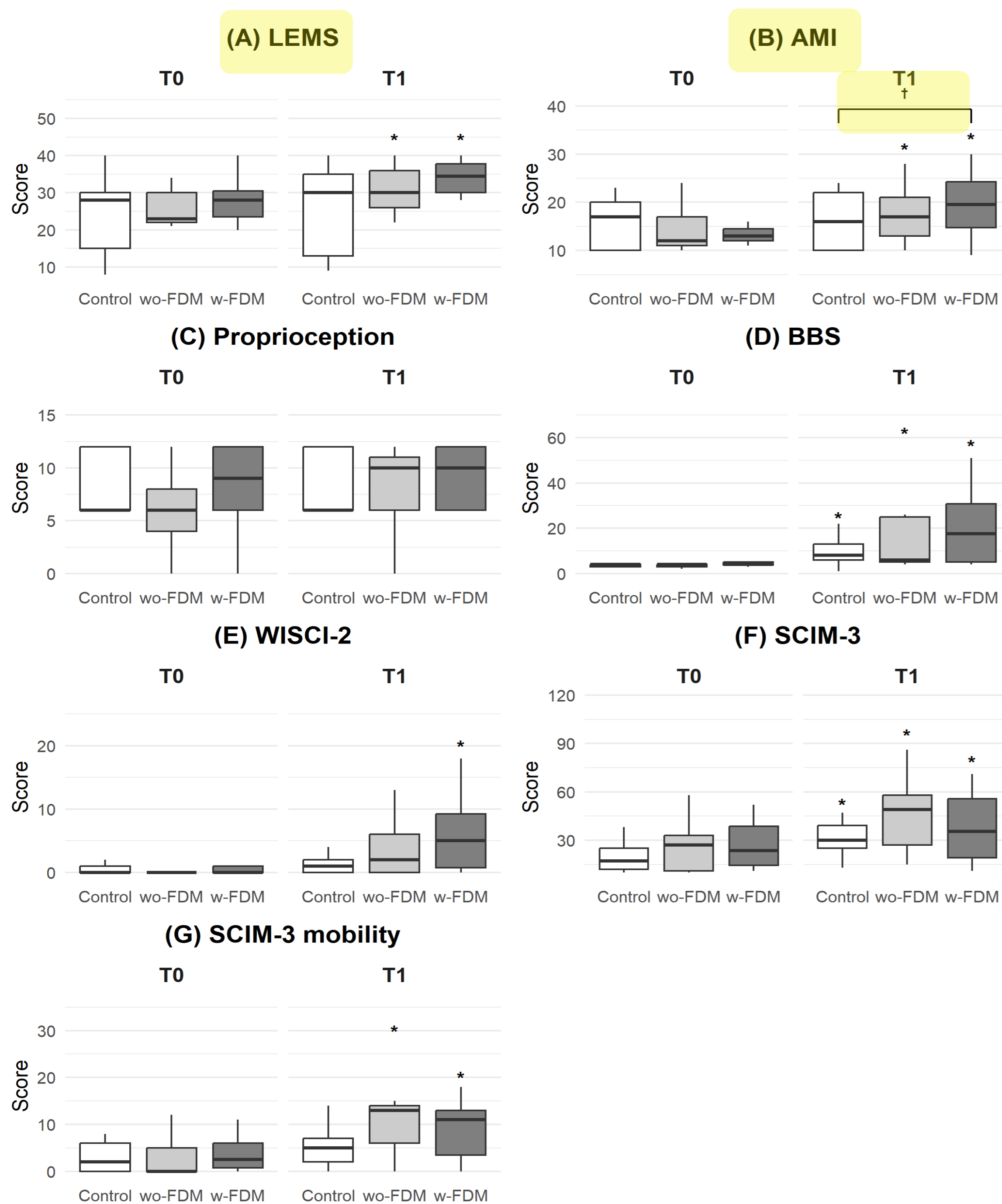


Figure 1. Study flow diagram showing participant enrollment, randomization, and analysis.

Figure 2. Post intervention changes in motor, sensory, and functional outcomes across groups.

*within-group $p < 0.05$; †between-group $p < 0.05$.



This was an exploratory randomized controlled trial including individuals with incomplete SCI.

Participants were randomly assigned to one of three groups: **control**, conventional Lokomat training without FreeD (**wo-FDM**), and Lokomat training with FreeD (**w-FDM**). All groups received 20 training sessions over four weeks.

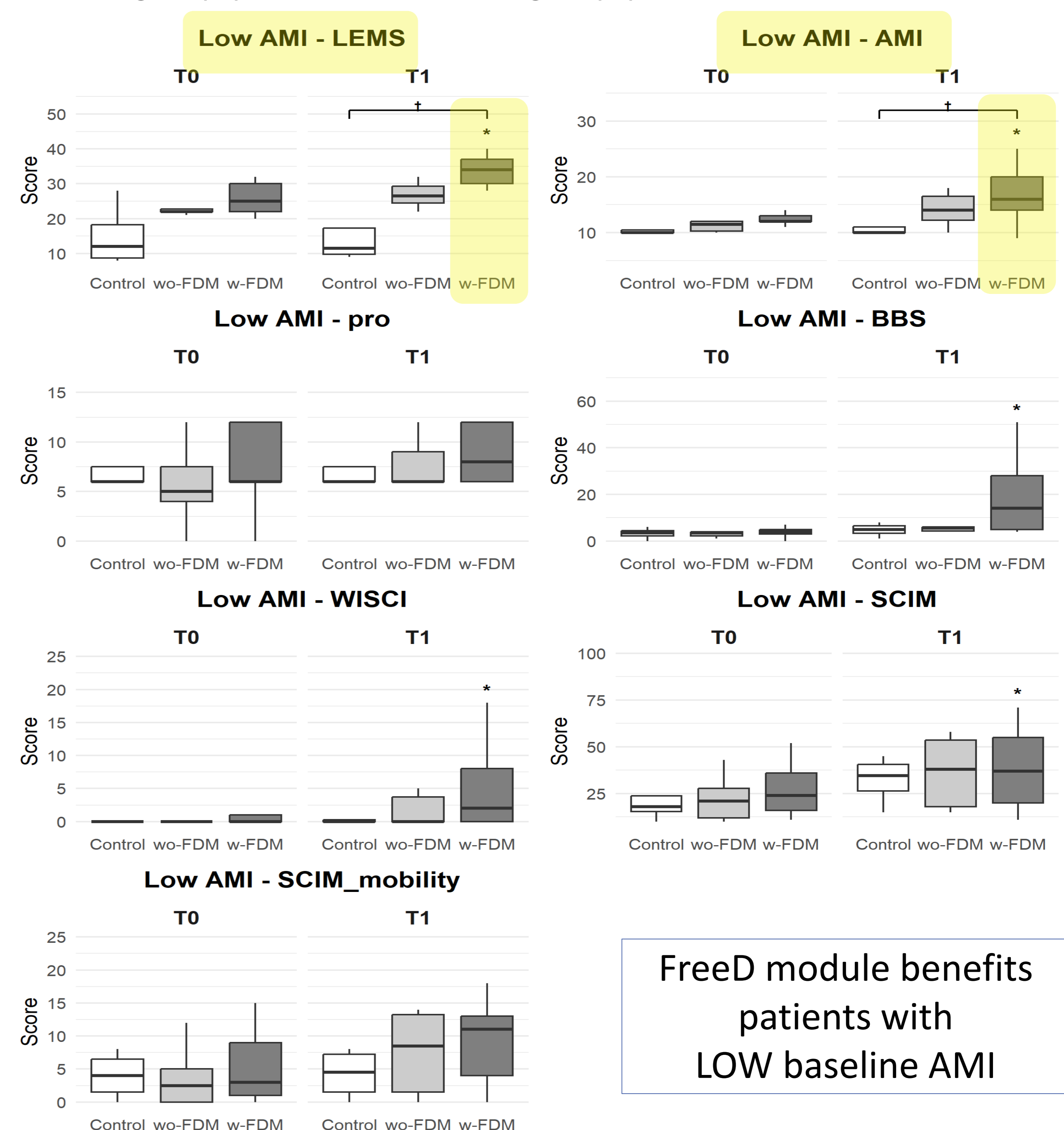
Primary outcomes included the Lower Extremity Motor Score (LEMS), Ambulatory Motor Index (AMI), and proprioception. Secondary outcomes were the Berg Balance Scale (BBS), Walking Index for Spinal Cord Injury II (WISCI-II), and Spinal Cord Independence Measure III (SCIM-III).

Subgroup analyses were performed based on baseline AMI (<15.6 vs ≥ 15.6) to evaluate differential treatment effects.

Results

- Both Lokomat groups (wo-FDM and w-FDM) showed significant within-group improvements in LEMS and AMI.
- The w-FDM group demonstrated greater improvement in AMI compared with the control group ($p=0.037$).
- In participants with low baseline AMI (<15.6), the w-FDM group showed significantly greater improvements in both LEMS and AMI (both $p=0.009$).
- No additional benefit of FreeD was observed in participants with higher baseline AMI (≥ 15.6).
- No intervention-related adverse events were reported.

Figure 3. Subgroup analysis of participants with *low baseline AMI* (<15.6). *within-group $p < 0.05$; †between-group $p < 0.05$.



FreeD module benefits patients with LOW baseline AMI

Conclusion

FreeD-enabled RAGT was safe and associated with greater motor improvement, particularly in individuals with low baseline ambulatory capacity.

These findings suggest that the therapeutic benefit of FreeD depends on initial motor function, supporting a personalized approach to robotic gait rehabilitation.

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