

Digital Gait Characteristics as Indicators of Muscle Strength in Chronic Inflammatory Demyelinating Polyneuropathy

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Background

Chronic inflammatory demyelinating polyneuropathy (CIPD) is an immune-mediated neuropathy in which muscle weakness and impaired mobility are core drivers of disability¹. Established assessments — the Inflammatory Neuropathy Cause and Treatment (INCAT) disability scale, grip strength and the Medical Research Council (MRC) Sum Score — are clinician-rated measures of impairment and disability, but have limited responsiveness to clinically meaningful change and their capacity to anticipate treatment response is not well established². Measures that better capture treatment response remain a need in CIPD.

ARISE (NCT05327114) is a Phase 2/3 randomised, double-blind, placebo-controlled withdrawal study of nivalimab in adults with active CIPD, in which digital gait assessment was included as an exploratory objective to evaluate gait change as a marker of disease course and treatment response.

Wearable sensors allow objective, low-burden quantification of gait and may provide complementary information on neuromuscular function in CIPD^{3,4}.

Objectives

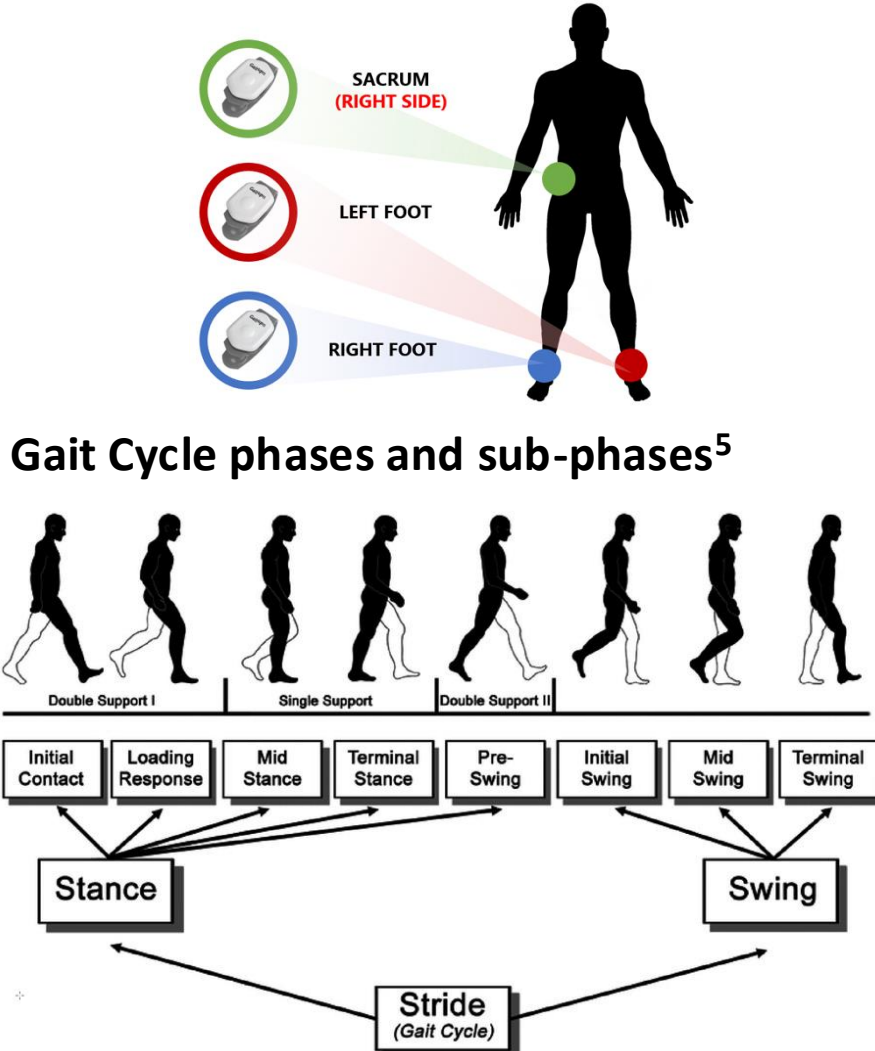
To evaluate the relationship between digital gait characteristics derived from wearable sensors and established clinical assessments of muscle strength and disability in participants with active CIPD, and to assess the feasibility of collecting these measures within a global Phase 2/3 study.

Methods

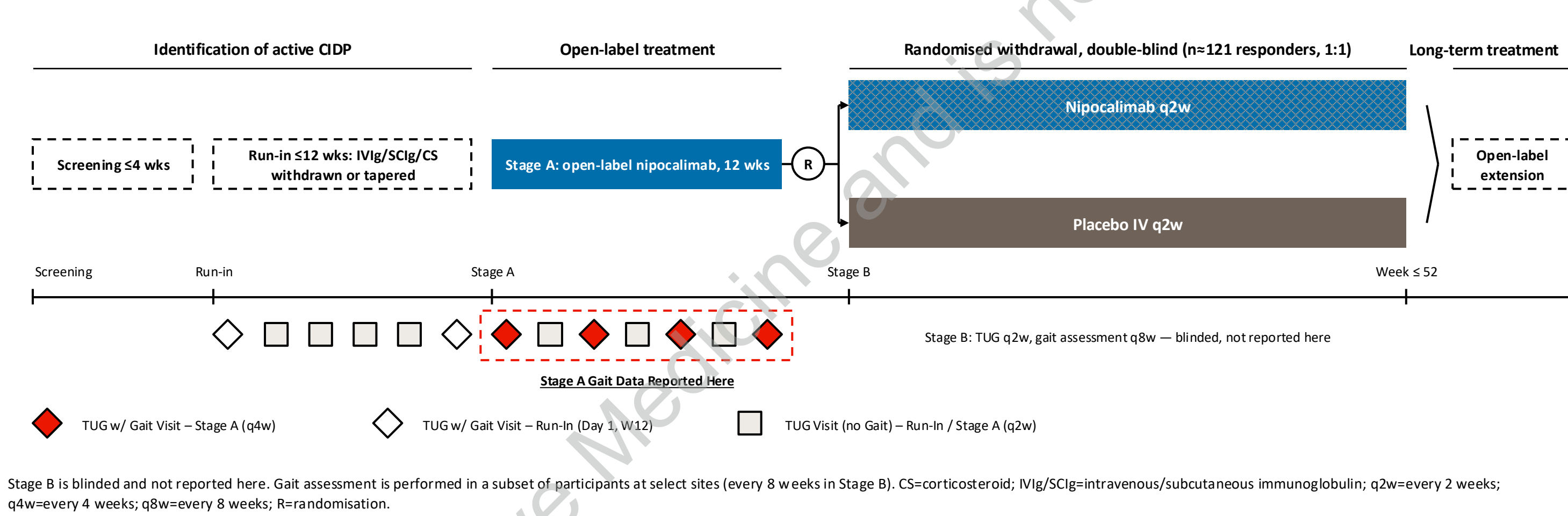
Study design and digital gait assessment

- Analyses were restricted to Stage A, in which all participants received open-label nivalimab for a fixed duration of 12 wks, to preserve a homogeneous population and a clean interpretation; Stage B remains blinded and is not included in this analysis.
- Gait assessment: NeuroX™ foot- and sacrum-mounted accelerometers during the Timed Up and Go (TUG) test at scheduled site visits; 23 gait parameters per test, in a subset of participants at select sites
- Clinical outcomes (INCAT disability scale, grip strength, MRC Sum Score) captured at matched visits
- Repeated-measures correlations (rmcorr) against clinical outcomes with False Discovery Rate (FDR)-adjusted p-values; August 2026 data cut

Accelerometer placement



Study Design & Schedule of Activities



Results

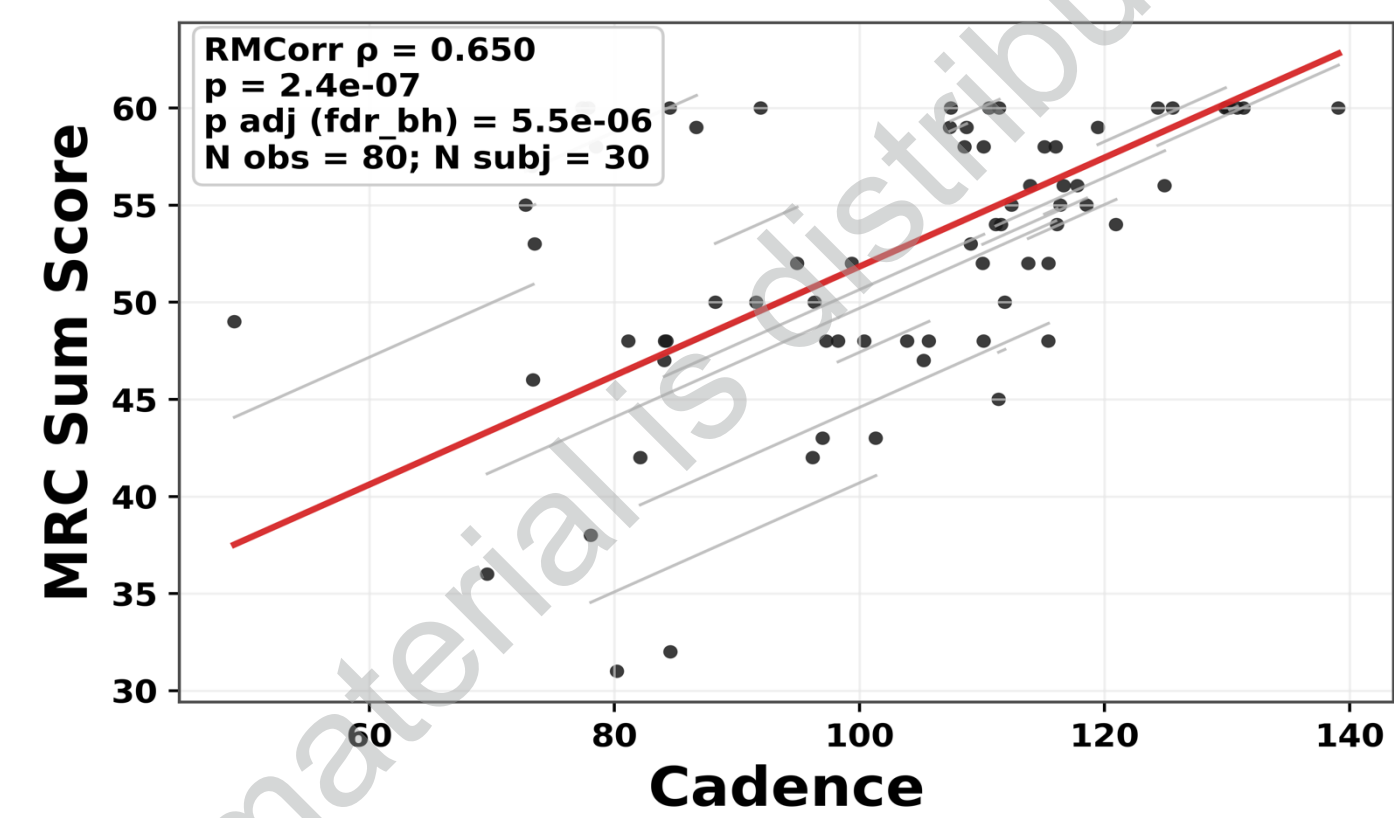
Table 1. Demographics and baseline disease characteristics — Stage A analysis set

Baseline Characteristics		Stage A analysis set (N = 30)
Demographics		
	Age, years, mean (SD)	58.2 (12.6)
	Female	6 (20%)
	Race, Asian/Black/White/Not reported	0/1/19/10 (0/3/63/33%)
	Region, Europe/North America/Other	22/7/1 (73/23/3%)
Disease Characteristics		
	CIPD disease duration, yrs, mean (SD)	6.6 (6.6)
	CIPD subtype, typical/variant	15/15 (50%/50%)
	INCAT disability scale	
	Baseline, mean (SD)	4.5 (1.5)
	Moderate–severe (≥4)	24 (80%)
	MRC Sum Score (0–60), mean (SD)	50.9 (6.2)
Gait Data Quality (Stage A analysis set)		
	Participants missing ≥1 Gait visits	24 (80%)
	Early withdrawal	6 (20%)
	Technical issue	1 (3%)
	Missingness, unexplained	17 (57%)
Treatment Status at Screening		
	On treatment	7 (23%)
	Off treatment	7 (23%)
	Treatment naïve / <3 months	5 (17%)
	Not available	11 (37%)

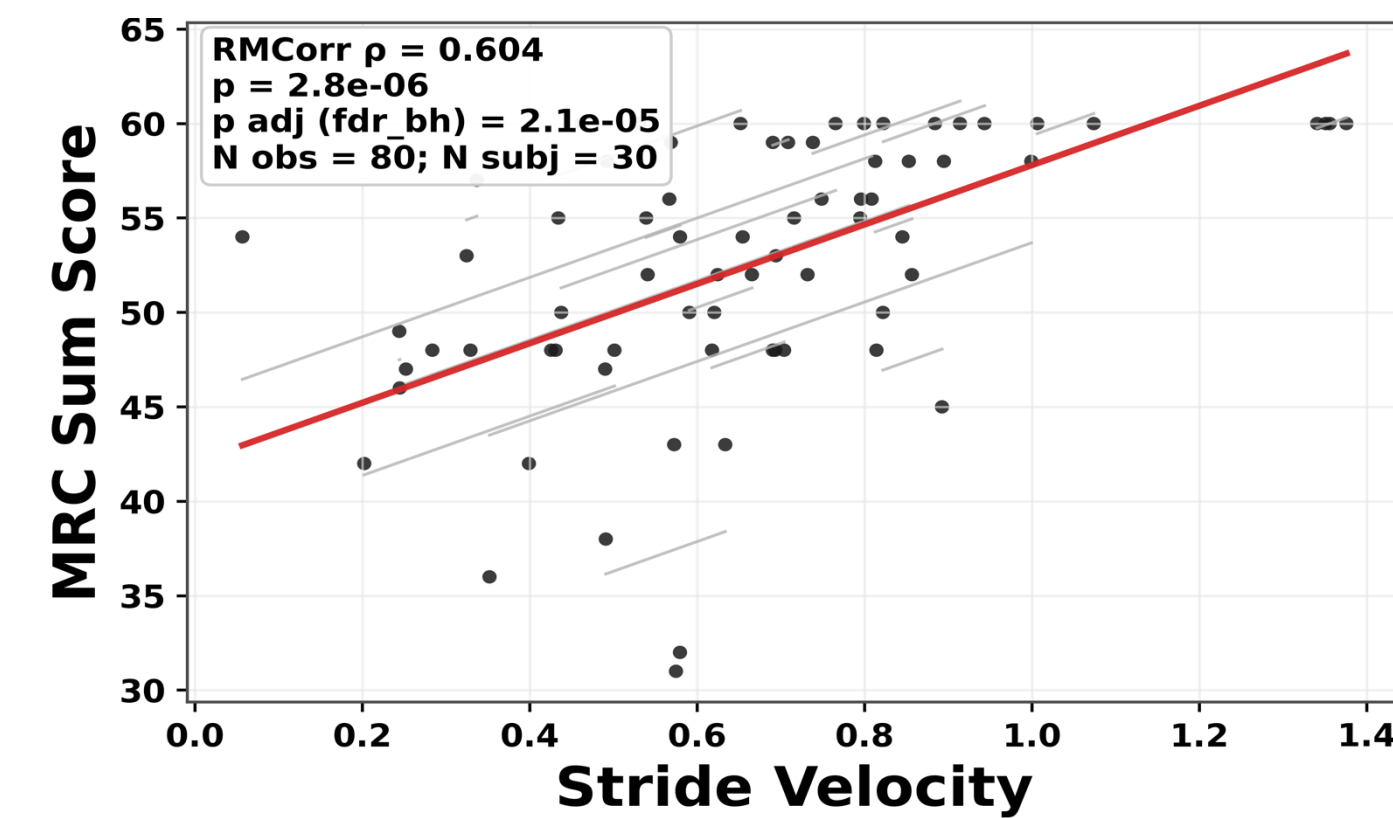
IVig=intravenous immunoglobulin; SCig=subcutaneous immunoglobulin; SD=standard deviation.

Figure 1. Association of digital gait characteristics with measures of muscle strength

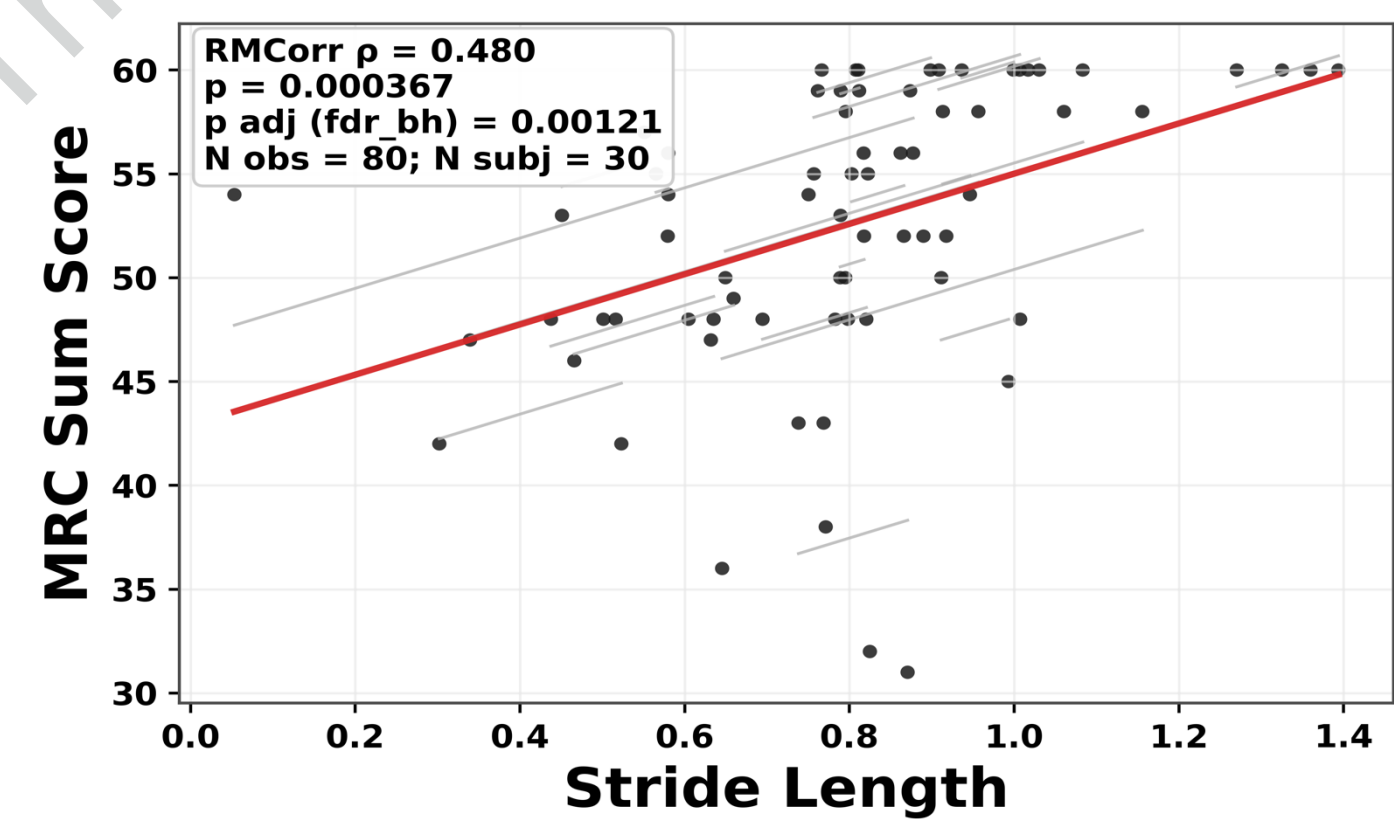
A. Cadence (steps/min) vs MRC Sum Score (points)



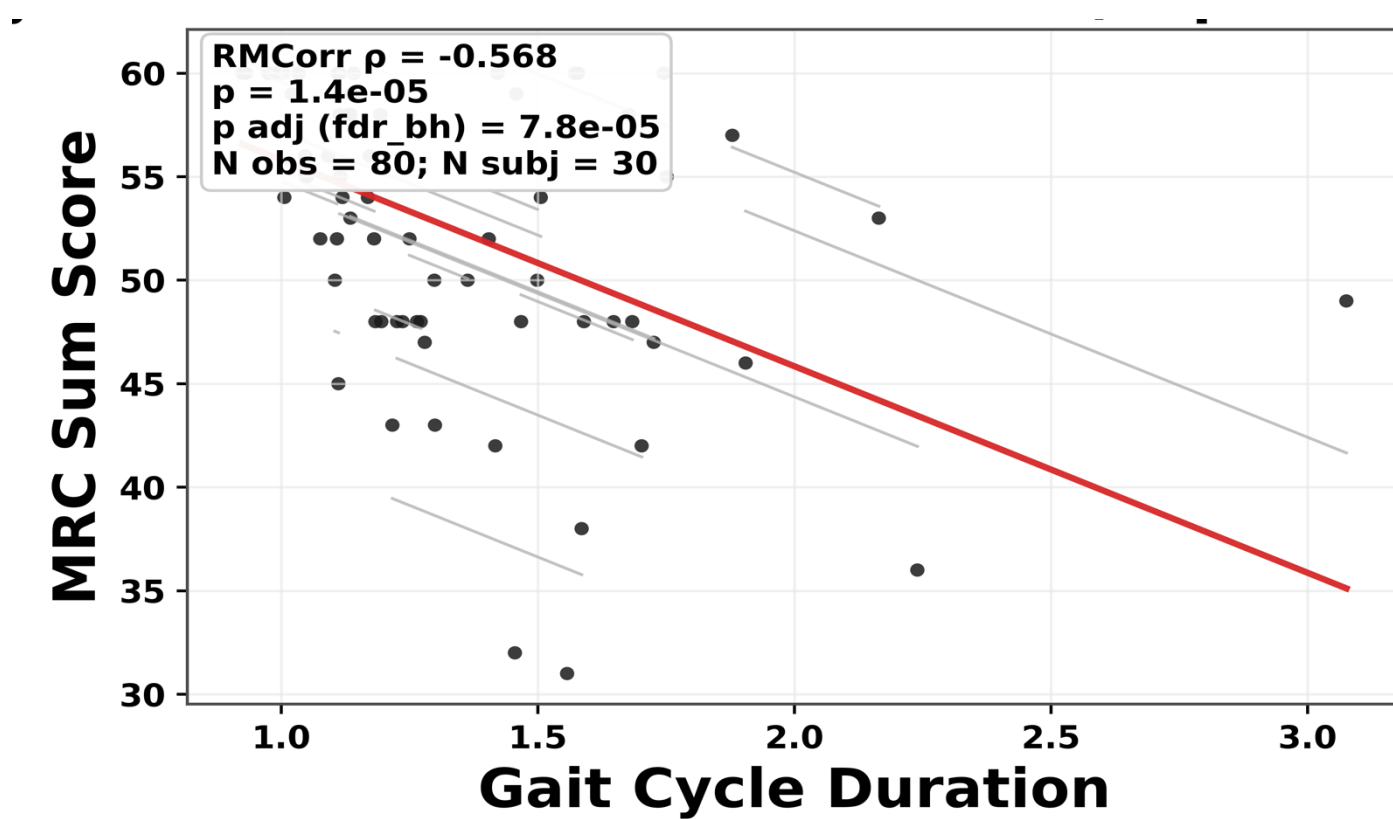
B. Stride velocity (m/s) vs MRC Sum Score (points)



C. Stride length (m) vs MRC Sum Score (points)



D. Gait cycle duration (s) vs MRC Sum Score (points)



Panels A–D show repeated-measures correlations (rmcorr) between MRC Sum Score (points) and each digital gait characteristic across Stage A visits; the red line is the overall association and grey lines are within-participant fits. Greater muscle strength is associated with faster cadence, higher stride velocity and longer stride length (A–C), whereas a longer gait cycle duration is associated with lower strength (D).



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Key Takeaways

- Digital gait characteristics captured with wearable sensors during the Timed Up and Go test correlated with established measures of muscle strength in participants with active CIPD.
- Cadence, stride velocity, stride length and gait cycle duration showed the most consistent associations with the MRC Sum Score; a consistent trend was observed for grip strength (not shown).
- With robust operational oversight and optimization, digital gait assessment may be a feasible, potentially low-burden complement to conventional clinical outcome measures in CIPD.

Figure 2. Distribution of cadence (steps/min) by MRC Sum Score, INCAT disability scale and grip strength

Cadence distributions across strength and disability strata. Participants with lower MRC Sum Scores walked with a lower cadence, and cadence declined further with increasing INCAT disability — supporting cadence as a functional marker of disease severity in active CIPD.

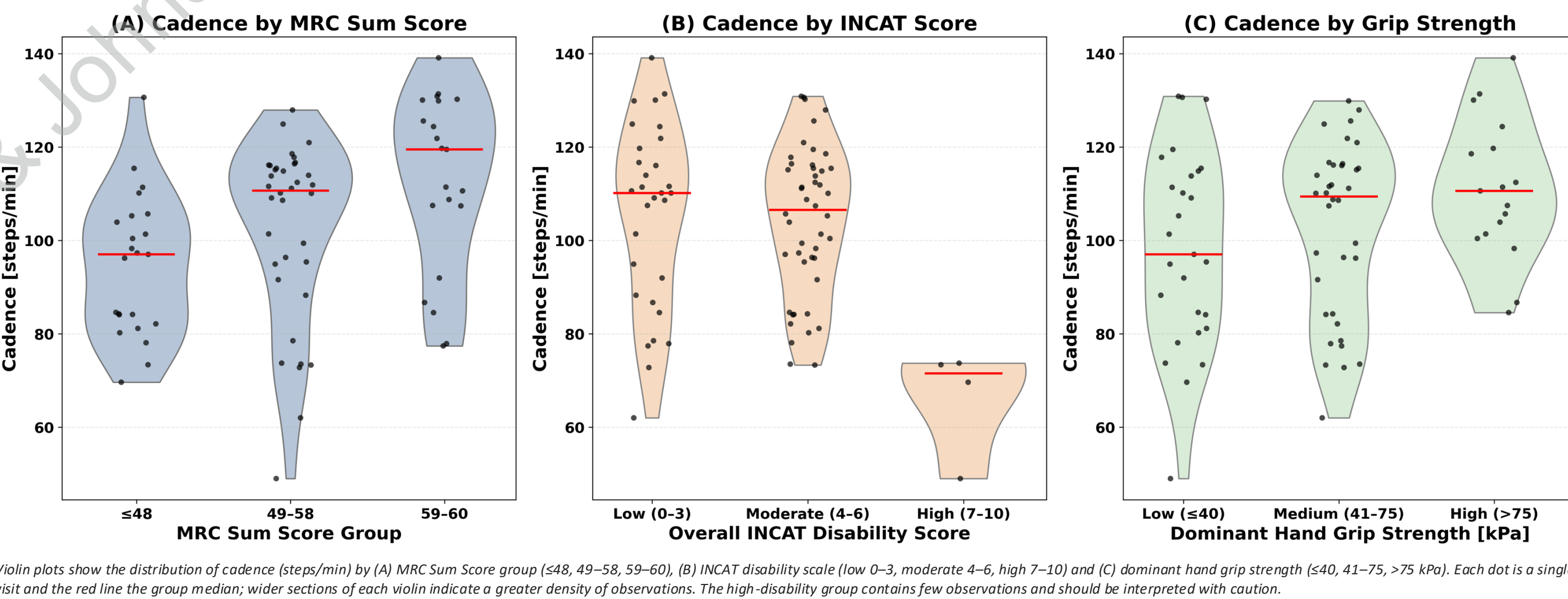
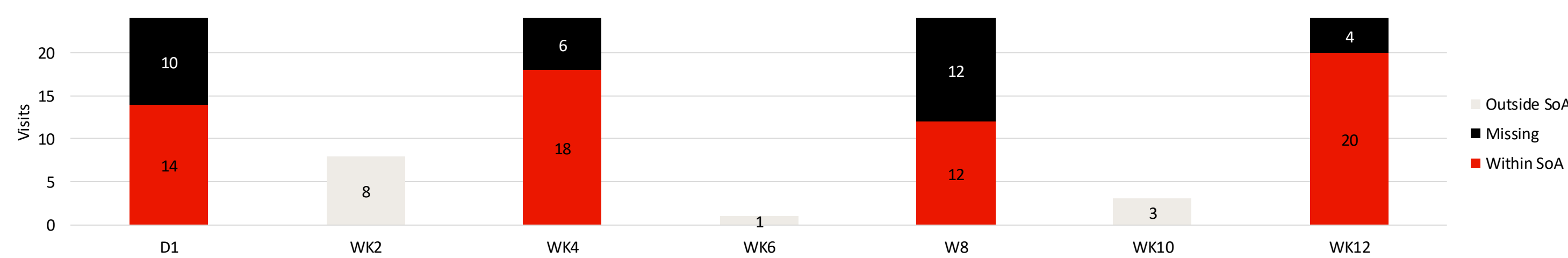


Figure 3. Distribution of gait recording visits in Stage A, excluding early withdrawals

Columns show the distribution of gait recording visits for participants that completed Stage A (N=24). Missingness (black) and the occurrence of data capture outside of the expected Schedule of Activities (SoA, grey) are displayed; expected Stage A recording window: Day 1 (D1), Week 4 (WK4), Week 8 (WK8), and Week 12 (WK12).



Feasibility and operational learnings

- Incomplete recording sets:** Complete Stage A recording sets were available for 6/30 participants (20%); among the 24 who completed Stage A, visit gaps were common, potentially limiting assessment of measurement stability.
- Sources of missingness (N=30):** early withdrawal 6 (20%), a single device processing error affecting one visit 1 (3%), and 17 (57%) unexplained, with missingness peaking at Week 8.
- Off-schedule assessments:** 8 at Week 2, 1 at Week 6 and 3 at Week 10 — largely not catch-up attempts, suggesting the schedule of activities was either unclearly communicated or unnecessarily complex (TUG every 2 weeks vs. sensors every 4 weeks).

Discussion

Technical considerations:

- Off-schedule recordings (Weeks 2, 6, 10) point to a schedule that was unclear or overly complex.
- Connectivity delays and sensor unpairing/position swaps may require close site monitoring.
- Path forward: Direct site monitoring mitigated these issues; refinements to solution design, documentation and site readiness could reduce that burden and improve data consistency in future studies.

Key findings:

- Cadence, stride velocity, stride length and gait cycle duration — measures of walking rhythm and step generation — tracked muscle strength most consistently, with a consistent trend for grip strength (not shown); this is coherent with weakness in CIPD slowing and shortening the gait cycle, and suggests that a small set of interpretable parameters may suffice for future assessment.
- NeuroX™ sensor-derived gait measures correlated with conventional muscle strength outcomes in active CIPD, supporting sensor-derived gait as an objective complement to clinician-rated strength measures, and extending prior observations of digital activity markers in CIPD⁴ to sensor-derived gait.
- Device-attributable data loss was minimal (one visit lost to a processing error); missingness was driven predominantly by operational and scheduling factors, which are addressable.
- Associations reported here are concurrent, i.e. between gait and strength at matched visits.