A Multi-Source Validation Framework for Smartphone-Based Walk Tests

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What is the Methodological Issue Being Addressed? Evaluating smartphone-based walk tests as digital mobility endpoints requires evidence from multiple complementary sources rather than a single validation study. A fit-for-purpose assessment must integrate complementary evidence spanning technical performance, benchmarking, cross-platform consistency, and external validation. Here we address the methodological problem of how to organize these distinct evidence sources into a coherent framework for judging the readiness of smartphone-based 2-Minute Walk Test (2MWT) and 6-Minute Walk Test (6MWT) assessments.

Introduction The 2MWT and 6MWT are widely used assessments of functional mobility across neurological and chronic disease populations. These assessments are traditionally conducted in person using standardized walking courses and trained personnel, creating logistical and operational burdens for large-scale or remote studies. Smartphone-based implementations offer a scalable, low-burden approach to remote mobility assessment using participants' own devices and may facilitate more frequent and geographically distributed mobility assessments. However, establishing confidence in these measures requires evidence from multiple complementary evaluation approaches.

Methods Four evidence streams were evaluated. First, external benchmarking against Mobilise-D gait-speed references. Second, cross-platform harmonization using simultaneous iOS and Android recordings in healthy adults (n=2, 5 repetitions) and people with Parkinson's disease (n=3, 9 repetitions). Third, analytical validation of smartphone-derived 6MWT outcomes against video reference measurements in healthy adults (n=6, 8 repetitions). Fourth, independent validation of smartphone-derived 2MWT outcomes against manual reference measurements in healthy adults (n=37).
External benchmarking assessed agreement with published reference ranges, cross-platform harmonization employed Bland-Altman analyses and percentage differences, analytical validation employed MAPE with 95% Confidence Interval (95%CI), and independent validation employed Bland-Altman and correlation analyses.

Results Across the multi-source framework, smartphone-based walk tests showed supportive findings in four complementary evidence streams.
In external benchmarking, algorithm-derived gait speed demonstrated directional alignment with Mobilise-D cohort-level reference values, remaining numerically close to the published mean and within the reported confidence interval.

In cross-platform harmonization, iOS and Android recordings showed consistent step detection performance, with a Bland-Altman bias of 0.21 steps and all observations falling within the limits of agreement (LoA) (LoA: -6.13 to 6.56 steps). The mean percentage difference was 1.56% (95% CI: 0.36-2.94).
In analytical validation, smartphone-derived 6MWT outcomes demonstrated low error relative to video reference measurements, with MAPE values of 0.59% (95% CI: 0.00-1.54) for distance, 0.60% (95% CI: 0.00-2.91) for turn detection, and 6.41% (95% CI: 2.21-10.60) for step detection.
In independent validation, smartphone-derived 2MWT outcomes demonstrated agreement with reference measurements, with a distance bias of 5.79 m (LoA: -19.18 to 30.77 m, with 94.6% of samples within the LoA) and a turn detection bias of 0.41 turns (91.9% within the LoA: -1.16 to 1.97). Strong correlations were observed for distance (ρ=0.88, $p<0.001$) and turn counts (ρ=0.90, $p<0.001$).

Conclusion A multi-source validation framework can provide a structured approach for evaluating smartphone-based mobility endpoints. Convergent evidence from benchmarking, cross-platform harmonization, analytical validation, and independent validation supported the fit-for-purpose use of smartphone-derived 2MWT and 6MWT outcomes. This framework may help guide evidence generation and readiness assessments for digital mobility measures intended for clinical research and future clinical validation.

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Disclosures Jacqueline Lutz serves as a fractional Chief Scientific Officer and consultant to Beats Medical. Co-authors Mariana Abreu, PhD is employee and Ciara Clancy, PhD is CEO of Beats Medical.

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