The construct validity of real-world digital mobility outcomes in people with COPD

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17 digital mobility outcomes (DMOs) quantifying walking activity and gait exhibit construct validity, following assessment of convergent, divergent and known-groups validity, supporting their use as objective, clinically meaningful biomarkers in COPD https://bit.ly/4nUIYBg

Cite this article as: Megaritis D, Long M, de las Heras M, *et al*. The construct validity of real-world digital mobility outcomes in people with COPD. *ERJ Open Res* 2026; 12: 00993-2025 [DOI: 10.1183/23120541.00993-2025].

Abstract

Background Recent advances in wearable technologies make it possible to accurately quantify real-world mobility performance through technically validated digital mobility outcomes (DMOs). The aim of the present study was to evaluate the construct validity (convergent, divergent, and known-groups validity) of 24 DMOs quantifying walking activity (amount and pattern) and gait (pace, rhythm and bout-to-bout variability) in people with COPD.

Methods Part of the Mobilise-D observational cohort study, people with COPD, recruited from seven European sites, wore an activity monitor for 7 days during daily life. Functional capacity, health status, dyspnoea, lung function, quadriceps torque and experience of difficulty with physical activity were used as constructs for convergent validity testing (Pearson/Spearman correlation coefficients). Diastolic blood pressure was used as an unrelated construct for divergent validity (criterion: $|r|<0.2$). Known-groups

Received: 24 July 2025
Accepted: 5 Nov 2025

validity was evaluated across Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages (I–IV), GOLD ABE and modified Medical Research Council dyspnoea grades (linear models with p-for-trend).

Results 549 participants (37% females), had mean±SD age of 68±8 years, post-bronchodilator forced expiratory volume in 1 s (FEV_1) 54±20% predicted and 6-min walk distance 416±119 m. Convergent validity was supported for the majority of DMOs (17 out of 24) with correlation coefficients meeting or exceeding the *a priori* hypotheses by clinical experts. All DMOs supported divergent validity. 22 out of 24 DMOs distinguished between disease severity groups successfully. Expert consensus supported construct validity of 17 DMOs.

Conclusions Construct validity was supported for all walking activity (amount and pattern) DMOs, and most of the gait (pace, rhythm, and bout-to-bout variability) DMOs, indicating the clinical utility of these measures.

Introduction

The assessment of mobility performance in people with COPD during daily life has predominantly been limited to the amount that they walk (*e.g.* steps·day^{-1}, daily walking time) [1, 2]. While these are well-established prognostic markers in COPD [1, 3], they do not capture the full spectrum of mobility impairments present in this population [3–5]. Research in other long-term conditions [2] and our preliminary evidence in COPD [6–8] suggest that spatiotemporal mobility outcomes such as stride length, cadence and walking speed provide additional insights, and are valid and sensitive to disease progression-induced mobility impairment. However, due to technical complexity, the validation of such outcomes has so far been limited to laboratory settings [2], hindering translation to the real world.

Walking-related digital mobility outcomes (DMOs) are technically valid measurements of a person's mobility performance [9–11]. Wearable devices equipped with inertial measurement units enable the quantification of mobility [9, 12–14], allowing a detailed evaluation of real-world walking performance. The Mobilise-D project developed a processing pipeline to calculate DMOs encompassing both walking activity (in the domains of amount and pattern) and gait (in the domains of pace, rhythm and bout-to-bout variability) across diverse health conditions, including COPD [13]. The resulting DMOs exhibited good to excellent criterion validity in people with COPD [13, 14]. However, their construct validity (whether DMOs accurately reflect the specific aspects of health they are intended to reflect) has only been reported for walking activity amount, using analytical approaches relying on proprietary software without established criterion validity [1, 2]. Construct validity is still to be determined for novel DMOs such as pattern (*e.g.* walking bout characteristics), pace (*e.g.* walking speed), rhythm (*e.g.* cadence) and bout-to-bout variability (*e.g.* walking speed bout-to-bout variability).

Therefore, the aim of the present study was to assess the construct validity of real-world walking activity and gait DMOs derived from a recently proposed, open-source and technically valid computational pipeline [9, 13] in a large, heterogeneous, international sample of people with COPD across Europe. We pre-specified a set of *a priori* hypotheses, based on pilot data and structured expert input, regarding expected correlations between DMOs and clinical constructs, in line with regulatory guidance that emphasises hypothesis-driven evaluation of construct validity for biomarkers and digital health technologies [15–17].

Methods

Study design

This cross-sectional analysis is part of the Mobilise-D clinical validation study (www.ISRCTN.com identifier 12051706), a multicentre observational cohort study aiming to validate novel DMOs in COPD, Parkinson disease, multiple sclerosis and proximal femur fracture [12]. This article reports on COPD results from database version 7.0 of the study.

Participants

COPD participants were recruited between April 2021 and May 2022 in seven cities across six countries: Leuven (Belgium), Barcelona (Spain), Newcastle and London (United Kingdom), Zurich (Switzerland), Großhansdorf (Germany) and Athens (Greece). Individuals with diagnosis-confirmed COPD (post-bronchodilator forced expiratory volume in 1 s (FEV_1)/forced vital capacity (FVC) <0.70 [18], as per Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines), smoking history of ⩾10 pack-years, clinical stability (⩾4 weeks after onset of the last exacerbation prior to inclusion), able to walk 4 m independently with or without walking aids, and willingness to wear a single wearable device for 7 days, were eligible for inclusion. Individuals having substantial limitation in mobility due to factors unrelated to COPD, having a diagnosis of active lung cancer or primary respiratory disease other than

COPD, having undergone major lung surgery or lung volume reduction surgery within 6 months prior to inclusion, were excluded, as reported previously [12]. The study was approved by all local ethical committees and all participants provided written informed consent. Information on the baseline characteristics of the cohort were published previously [8, 19].

DMOs

Walking activity and gait were measured for 7 days using one of two metrologically equivalent single wearable devices positioned on the lower back at the level of the lumbar spine (L4–5): the MoveMonitor+ (McRoberts, The Hague, The Netherlands), worn on a belt around the waist, only removed for bathing/swimming; or the Axivity AX6 (Newcastle Upon Tyne, UK), fixed to the participants' skin at the lower back using a patch. Both were equipped with a three-axial accelerometer (±8 *g*, 1 mg resolution) and a three-axial gyroscope (±2000°·s^{-1}, 70°·s^{-1} resolution), collecting data at 100 Hz. We removed participants who did not have a minimum of >12 h of daily wear time (07:00–22:00 h) across ⩾3 days [20]. Using Mobilise-D algorithms, we first identified walking bouts (walking sequence containing at least two consecutive strides of both feet [21]), and obtained walking bout-level DMOs, which were previously validated against gold and silver standards for their criterion validity [13, 14]. We then calculated weekly-aggregated DMOs, as outlined previously [22]. A total of 24 DMOs were obtained, encompassing walking activity (amount and pattern) and gait (pace, rhythm, and bout-to-bout variability) domains. DMO definitions, and units have been published previously [8] and a concise description is presented in supplementary table S2. Briefly, in the walking activity category, the amount domain captured daily walking duration and walking bout step count, while the pattern domain captured the daily number of walking bouts of different durations. In the gait category, the pace domain captured walking speed and stride length; the rhythm domain captured cadence and stride duration; and the bout-to-bout variability domain captured the variability of DMOs across walking bouts within a day. These DMOs were measured and reported in a diverse range of walking bout durations (all walking bouts, >10 s, 10–30 s, >30 s). Daily DMO values were first computed as the average of all walking-bout-level values within each day or, for peak metrics, as the 90th percentile of the daily walking bout values. Weekly values were then derived by averaging the corresponding daily values over seven consecutive days.

Constructs

Clinical constructs included 1) functional exercise capacity, using the 6-min walk test, according to the European Respiratory Society (ERS)/American Thoracic Society standard [23]; 2) health status, measured using the COPD Assessment Test (CAT); 3) dyspnoea, using the modified Medical Research Council (mMRC) scale; 4) lung function, including post-bronchodilator FEV_1, and FVC according to the ERS standards [18]; 5) quadriceps maximum voluntary contraction (QMVC), using isokinetic dynamometer at 90° knee/hip angles (torque=force × limb length (Nm)); 6) experienced difficulty with physical activity, using the Clinical visit PROactive Physical Activity in COPD tool (C-PPAC) [24]; 7) number of moderate-to-severe COPD exacerbations in the past 12 months from medical history and self-report; 8) GOLD I–IV, GOLD ABE [25]; and 9) diastolic blood pressure.

Statistical analysis

Assuming an α-level of 0.05 and a power of 80%, we estimated that detecting statistically significant correlations of ⩾0.5, ⩾0.4 and ⩾0.2 would require 29, 46 and 193 participants, respectively, using Fisher's z-test. Hence, our available sample size was deemed to provide sufficient power for the planned analyses.

Statistical analysis was planned *a priori* and conducted using R (v4.4.0). The analysis used a pairwise complete-case approach, including only observations where both the DMO and the corresponding construct measure were available. Participant characteristics and DMOs were described using mean±SD or median (interquartile range), depending on their distribution.

Pearson (r) or Spearman (ρ) coefficients with their 95% confidence intervals were used between the 24 DMOs and all constructs. Each DMO–construct pair was considered to hold convergent validity if it met the expected correlation coefficients anticipated from pilot study results [7] and expert consultation (supplementary table S3) or exceeded them up to a maximum of 0.9, indicating that the DMO provides the same information as existing constructs [26]. Subgroup analysis of convergent validity was conducted for age tertiles (⩽64, 65–72 and ⩾73 years), sex, recruitment site (collapsed into three categories: Mediterranean (Athens, Barcelona), Oceanic (London, Leuven, Newcastle) and Continental (Zurich, Großhansdorf), and occurrence of previous exacerbations. No strata were excluded, since they met the minimum sample size requirements.

Divergent validity was assessed by testing the correlations of each of the DMOs with diastolic blood pressure, *a priori* expected to have no relationship with any of the DMOs. Divergent validity was supported when $|r/\rho|<0.2$.

Known-groups validity was assessed by testing the distribution of DMOs according to the groups defined by GOLD I–IV, GOLD ABE and mMRC, and supported when p-for-trend from linear regression models was $\leqslant 0.05$.

Finally, construct validity was established through expert consensus. A group of nine experts from diverse backgrounds (respiratory medicine, epidemiology, physiotherapy, exercise physiology and data science) assessed each DMO individually, evaluating their validity based on the pre-defined assumptions described earlier. Each expert independently assessed the validity of each DMO and final decisions on whether a DMO demonstrated construct validity were made in a consensus meeting. During the initial stage, each expert independently assessed each DMO in a blinded manner, without access to other experts' responses. During the consensus meeting, discrepancies between experts were discussed to identify the reasoning behind differing opinions and ensure transparency, after which a consensus was reached, supported by all experts. The distribution of votes for each DMO is reported to reflect the level of agreement among experts.

Results

From a total of 607 recruited participants, 38 did not have any DMO data and 20 did not meet the aforementioned DMO data inclusion criteria with respect to either the number of needed days or the required hours per day; the remaining 549 (90%) were included in the analysis. There were no differences between included and excluded participants except for lower FVC % pred, and higher walking aid use in the included participants (supplementary table S1). The included sample (table 1) included 37% females. The overall mean±SD age was 68±8 years, and the mean±SD FEV_1 was 54±20% pred). Participants walked a median of 6561 steps·day^{-1}, during a mean of 296 walking bouts, with a 90th percentile (P90) walking speed in longer walking bouts of 0.99 m·s^{-1}, a cadence of 85 steps·min^{-1} and walking speed bout-to-bout variability in longer walking bouts of 17.2%.

Convergent validity

The walking activity amount domain DMOs provided moderate-to-strong correlations with related constructs ($|\rho|=0.20–0.67$) (table 2) consistent with the anticipated coefficients (supplementary table S3). Walking pattern DMOs provided weak-to-strong associations with related constructs ($|\rho|=0.08–0.64$), with most coefficients matching the expected values.

For pace domain DMOs, correlations with related constructs were small-to-strong ($|r|=0.07–0.65$), with the vast majority matching the expected coefficients. Rhythm DMOs provided small-to-strong coefficients ($|\rho/r|=0.06–0.67$), matching expectations for most constructs except for QMVC torque and CAT. Walking speed and stride length bout-to-bout variability provided weak-to-moderate correlations ($|r|=0.15–0.58$), but stride duration and cadence variability produced weak correlations ($|r|=0.00–0.35$) (table 2). Correlation coefficients were found to be comparable across age groups, sex, history of exacerbations and sites (figure 1, supplementary figures S1–S5).

Divergent validity

Weak correlations for all 24 DMOs were established with diastolic blood pressure ($|\rho|=0.01–0.17$) (table 2).

Known-groups validity

22 DMOs (all but stride duration in all walking bouts and stride duration bout-to-bout variability) were statistically differentiated across groups (GOLD I–IV, GOLD ABE and mMRC), suggesting known-groups validity (supplementary figures S6–S8).

Expert consensus on construct validity

There was consensus agreement regarding 17 DMOs that met construct validity. For 10 of them, there was unanimous agreement (100% voting), while for seven DMOs, there was a slight disagreement, and, after additional discussion, all were deemed to meet construct validity, with no justification to suggest otherwise based on the constructs used. Seven DMOs were considered not to meet construct validity (table 3).

Discussion

This is the first multisite study evaluating the construct validity of real-world DMOs, in a large COPD sample. Consensus identified 17 out of 24 DMOs supporting construct validity. Specifically, 1) all amount and pattern DMOs were supported by all validity analyses; 2) most of the pace and rhythm DMOs showed

TABLE 1 Sociodemographic and clinical characteristics of 549 people with COPD, recruited from seven sites in six European countries, 2021–2022

	All	GOLD 1	GOLD 2	GOLD 3	GOLD 4
Participants	549	62 (11)	235 (43)	178 (33)	74 (13)
Age years	68±8	67±8	68±8	68±8	65±7
Sex female	202 (37)	28 (45)	84 (36)	60 (34)	30 (41)
Recruitment site					
Athens	48 (9)	2 (3)	20 (9)	15 (8)	11 (15)
Barcelona	148 (27)	20 (32)	60 (26)	49 (28)	19 (26)
Grosshansdorf	132 (24)	18 (29)	65 (28)	38 (21)	11 (15)
Leuven	109 (20)	5 (8)	53 (23)	37 (21)	14 (19)
London	24 (4)	3 (5)	9 (4)	8 (4)	4 (5)
Newcastle	47 (9)	5 (8)	15 (6)	22 (12)	5 (7)
Zurich	41 (7)	9 (15)	13 (6)	9 (5)	10 (14)
BMI[#] kg·m^{-2}	28±5	27±4	29±5	27±5	26±6
Smoking pack-years	53±29	49±29	52±26	55±30	55±31
Dyspnoea (mMRC grade 0–4)[#]	2 (1–2)	1 (1–1)	1 (1–2)	2 (1–3)	2 (2–3)
CAT score (0–40)[#]	14 (9–19)	10 (6–17)	13 (8–18)	16 (11–20)	16 (12–23)
Isometric quadriceps muscle torque[#] N·m^{-1}	121±55	135±63	126±54	115±55	108±45
6MWD[#] m	416±119	483±103	444±100	395±124	320±108
FEV$_1$ % pred	54±20	90±9	64±8	40±5	25±4
FVC % pred	85±20	111±11	91±14	77±14	60±15
GOLD ABE[#]					
Group A: low symptom severity, low exacerbation risk	109 (20)	25 (40)	61 (26)	20 (11)	3 (4)
Group B: high symptom severity, low exacerbation risk	322 (59)	31 (50)	138 (59)	111 (62)	42 (57)
Group E: high exacerbation risk	107 (19)	6 (10)	28 (12)	45 (25)	28 (38)
ICS	328 (60)	24 (39)	119 (51)	125 (70)	60 (81)
Long-acting bronchodilator (LAMA and/or LABA)	472 (86)	41 66)	192 (82)	170 (96)	69 (93)
Short-acting bronchodilator (SAMA and/or SABA)	296 (54)	22 (35)	115 (49)	109 (61)	50 (68)
LAMA monotherapy	20 (4)	6 (10)	12 (5)	2 (1)	0 (0)
LABA and ICS	306 (56)	22 (35)	108 (46)	120 (67)	56 (75)
Triple therapy (LAMA+LABA+ICS)	263 (47)	9 (16)	92 (39)	110 (61)	52 (70)
Wearable device used					
Dynaport MoveMonitor	452 (82)	41 (66)	201 (86)	146 (82)	64 (86)
Axivity AX6	97 (18)	21 (34)	34 (14)	32 (18)	10 (14)
Walking aids (yes)	44 (8)	1 (2)	12 (5)	17 (10)	14 (19)
Physical Activity Experience (C-PPAC Scores, 0–100)[#]					
Amount	64±19	73±17	69±17	61±19	49±19
Difficulty	72±16	81±13	76±14	68±15	60±14
Total score	68±15	77±12	73±13	64±15	55±14
Diastolic blood pressure mmHg	80±13	83±10	80±12	80±14	79±12
Occurrence of moderate-to-severe exacerbations in 12 months prior to study inclusion	178 (32)	11 (6)	52 (29)	71 (40)	44 (25)

Data are presented as n, n (%), mean±SD or median (interquartile range). GOLD: Global Initiative for Chronic Obstructive Lung Disease; BMI: body mass index; mMRC: modified Medical Research Council dyspnoea score; CAT: COPD Assessment Test; 6MWD: 6-min walk distance; FEV$_1$: forced expiratory volume in 1 s; FVC: forced vital capacity; ICS: inhaled corticosteroids; LAMA: long-acting muscarinic antagonist; LABA: long-acting β-agonist; SAMA: short-acting muscarinic antagonist; SABA: short-acting β-agonist; C-PPAC: Clinical visit PROactive Physical Activity in COPD tool. [#]: some constructs had missing values: six in 6MWD, 15 in CAT, 25 in mMRC, 34 in isometric quadriceps muscle torque; seven in C-PPAC, 13 in GOLD ABE, two in diastolic blood pressure and seven in BMI.

construct validity, with correlation magnitudes varying between walking bout duration categorisation; and 3) half of the bout-to-bout variability DMOs supported all types of validity. Accordingly, DMOs capture the intended health aspects in COPD, providing reliable insights into patient health status. Notably, seven DMOs did not meet construct validity: the walking bout duration, four derived from short walking bouts alone (walking speed, cadence, stride length, stride duration), and two of bout-to-bout variability (cadence, stride duration), highlighting that the DMOs not meeting construct validity were those measured in or including short walking bouts.

Walking activity DMOs

Amount

Similar outcomes to the technically validated Mobilise-D walking activity amount DMOs have been widely applied in research and clinical settings for people with COPD [2]. They produced strong

https://doi.org/10.1183/23120541.00993-2025

TABLE 2 Distribution and convergent and divergent validity (correlation coefficients with corresponding 95% confidence intervals) of digital mobility outcomes (DMOs) in 549 people with COPD

	Median (IQR) or mean±SD [#]	Convergent validity						Divergent validity
		6MWD n=543	CAT n=534	mMRC n=524	FEV_1 % pred n=549	QMVC torque n=515	C-PPAC difficulty n=542	Diastolic blood pressure n=547
Walking activity								
Amount								
Walking duration min·day^{-1}	70 (44–104)	**0.66 (0.60, 0.71)**	**−0.34 (−0.41, −0.26)**	**−0.48 (−0.54, −0.40)**	**0.32 (0.24, 0.40)**	**0.20 (0.12, 0.28)**	**0.43 (0.36, 0.50)**	**0.10 (0.02, 0.18)**
Walking bout step count steps·day^{-1}	6578 (4023–9744)	**0.67 (0.61, 0.72)**	**−0.34 (−0.42, −0.26)**	**−0.48 (−0.55, −0.41)**	**0.33 (0.24, 0.40)**	**0.20 (0.11, 0.27)**	**0.44 (0.37, 0.50)**	**0.10 (0.02, 0.18)**
Pattern								
Number of walking bouts	295.7±137.9	**0.53 (0.47, 0.59)**	**−0.29 (−0.37, −0.21)**	**−0.42 (−0.50, −0.35)**	**0.29 (0.19, 0.37)**	0.08 (0.00, 0.16)	**0.37 (0.29, 0.44)**	**0.09 (0.01, 0.17)**
Number of walking bouts >10 s	121 (83–171)	**0.59 (0.53, 0.65)**	**−0.32 (−0.39, −0.24)**	**−0.45 (−0.52, −0.38)**	**0.31 (0.22, 0.39)**	0.19 (0.11, 0.28)	**0.40 (0.33, 0.47)**	**0.12 (0.03, 0.20)**
Number of walking bouts >30 s	19 (11–33)	**0.64 (0.58, 0.69)**	**−0.33 (−0.40, −0.25)**	**−0.47 (−0.53, −0.40)**	**0.28 (0.20, 0.36)**	**0.25 (0.17, 0.32)**	**0.42 (0.36, 0.50)**	**0.15 (0.07, 0.22)**
Number of walking bouts >60 s	6 (2–12)	**0.57 (0.50, 0.62)**	**−0.29 (−0.37, −0.20)**	**−0.41 (−0.48, −0.32)**	**0.26 (0.18, 0.34)**	0.19 (0.10, 0.26)	**0.35 (0.27, 0.43)**	**0.15 (0.07, 0.23)**
Walking bout duration s	8.9 (8.2–9.6)	**0.31 (0.24, 0.39)**	−0.15 (−0.23, −0.07)	**−0.22 (−0.30, −0.14)**	0.12 (0.03, 0.2)	**0.28 (0.20, 0.36)**	**0.21 (0.14, 0.29)**	**0.10 (0.02, 0.19)**
P90 walking bout duration s	24.9 (21.3–30.1)	**0.49 (0.41, 0.55)**	**−0.26 (−0.33, −0.18)**	**−0.35 (−0.42, −0.26)**	0.17 (0.07, 0.25)	**0.27 (0.19, 0.35)**	**0.32 (0.25, 0.40)**	**0.14 (0.06, 0.22)**
Walking bout duration bout-to-bout variability %	127.0 (93.7–179.1)	**0.51 (0.44, 0.57)**	**−0.22 (−0.30, −0.14)**	**−0.34 (−0.42, −0.26)**	**0.24 (0.16, 0.32)**	0.16 (0.09, 0.25)	**0.30 (0.22, 0.38)**	**0.09 (0.01, 0.17)**
Gait								
Pace								
Walking speed in shorter (10–30 s) walking bouts m·s^{-1}	0.67±0.07	0.36 (0.28, 0.43)	−0.11 (−0.20, −0.03)	−0.27 (−0.34, −0.18)	**0.20 (0.12, 0.28)**	0.19 (0.12, 0.27)	**0.22 (0.14, 0.3)**	**0.17 (0.08, 0.25)**
Walking speed in longer (>30 s) walking bouts m·s^{-1}	0.83±0.12	**0.54 (0.46, 0.59)**	**−0.21 (−0.29, −0.13)**	−0.36 (−0.43, −0.28)	**0.23 (0.15, 0.31)**	**0.25 (0.18, 0.33)**	**0.32 (0.24, 0.4)**	**0.15 (0.07, 0.23)**
P90 walking speed in walking bouts >10 s m·s^{-1}	0.9±0.13	**0.60 (0.54, 0.65)**	**−0.22 (−0.31, −0.14)**	**−0.40 (−0.47, −0.32)**	**0.24 (0.16, 0.32)**	**0.28 (0.21, 0.36)**	**0.35 (0.28, 0.43)**	**0.16 (0.07, 0.24)**
P90 walking speed in longer (>30 s) walking bouts m·s^{-1}	0.99±0.18	**0.67 (0.61, 0.71)**	**−0.24 (−0.32, −0.17)**	**−0.44 (−0.51, −0.37)**	**0.27 (0.19, 0.35)**	**0.29 (0.22, 0.36)**	**0.40 (0.32, 0.46)**	**0.16 (0.08, 0.24)**
Stride length in shorter (10–30 s) walking bouts m	0.91±0.09	**0.28 (0.20, 0.36)**	−0.06 (−0.13, 0.03)	**−0.21 (−0.29, −0.12)**	0.14 (0.06, 0.22)	**0.23 (0.16, 0.31)**	0.14 (0.06, 0.23)	**0.16 (0.07, 0.24)**
Stride length in longer (>30 s) walking bouts m	1.05±0.12	**0.40 (0.31, 0.47)**	−0.14 (−0.23, −0.06)	**−0.27 (−0.34, −0.19)**	0.16 (0.07, 0.25)	**0.26 (0.18, 0.33)**	**0.21 (0.13, 0.29)**	**0.14 (0.05, 0.21)**

Continued

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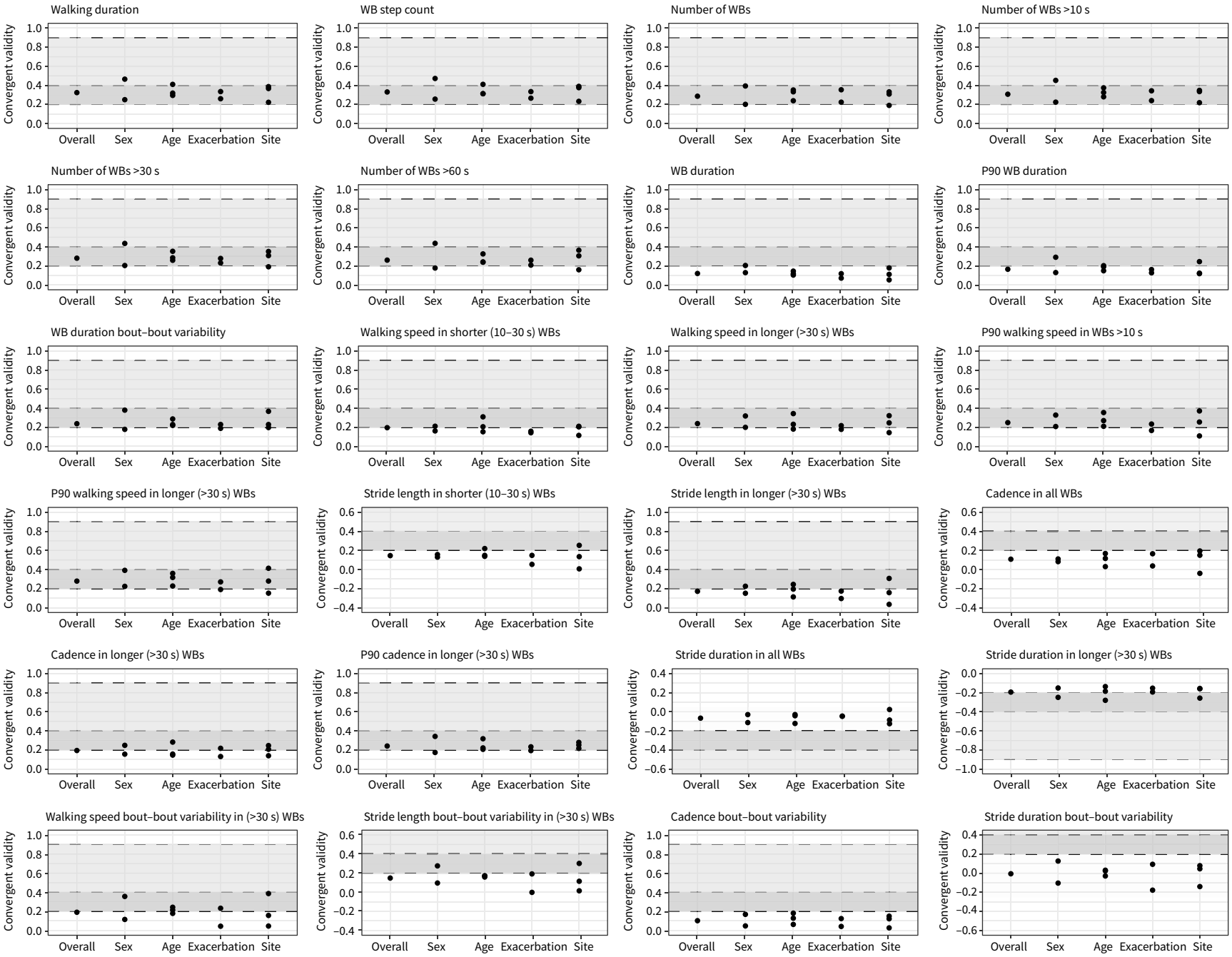
TABLE 2 Continued

	Median (IQR) or mean±SD [#]	Convergent validity						Divergent validity
		6MWD n=543	CAT n=534	mMRC n=524	FEV_1 % pred n=549	QMVC torque n=515	C-PPAC difficulty n=542	Diastolic blood pressure n=547
Rhythm								
Cadence in all walking bouts steps·min^{-1}	84.6±4.1	0.12 (0.03, 0.20)	−0.07 (−0.15, 0.02)	−0.08 (−0.17, 0.01)	0.12 (0.04, 0.19)	−0.06 (−0.14, 0.01)	0.10 (0.01, 0.18)	**0.01 (−0.07, 0.09)**
Cadence in longer (>30 s) walking bouts steps·min^{-1}	91.5±6.6	**0.39 (0.32, 0.45)**	−0.18 (−0.25, −0.11)	**−0.23 (−0.31, −0.14)**	**0.20 (0.12, 0.27)**	0.07 (−0.01, 0.15)	**0.26 (0.19, 0.34)**	**0.07 (−0.01, 0.15)**
P90 cadence in longer (>30 s) walking bouts steps·min^{-1}	100.1±8.6	**0.53 (0.48, 0.59)**	**−0.22 (−0.30, −0.14)**	**−0.31 (−0.39, −0.24)**	**0.24 (0.17, 0.32)**	0.10 (0.02, 0.18)	**0.35 (0.27, 0.43)**	**0.08 (0.00, 0.17)**
Stride duration in all walking bouts s	1.30±0.06	−0.13 (−0.21, −0.04)	0.06 (−0.03, 0.14)	0.11 (0.02, 0.18)	−0.07 (−0.15, 0.01)	0.00 (−0.09, 0.08)	−0.07 (−0.14, 0.01)	**0.01 (−0.07, 0.09)**
Stride duration in longer (>30 s) walking bouts s	1.26±0.09	**−0.34 (−0.41, −0.26)**	0.16 (0.08, 0.25)	**0.25 (0.18, 0.33)**	−0.19 (−0.28, −0.11)	−0.06 (−0.14, 0.02)	**−0.24 (−0.32, −0.16)**	**−0.04 (−0.13, 0.04)**
Bout-to-bout variability								
Walking speed bout-to bout variability in longer (>30 s) walking bouts %	17.2±5.2	**0.58 (0.52, 0.63)**	−0.16 (−0.24, −0.08)	**−0.35 (−0.42, −0.27)**	0.19 (0.10, 0.27)	**0.25 (0.16, 0.34)**	**0.34 (0.26, 0.41)**	**0.08 (0.00, 0.16)**
Stride length bout-to bout variability in longer (>30 s) walking bouts %	11.9±3.7	**0.48 (0.42, 0.54)**	−0.19 (−0.26, −0.11)	**−0.30 (−0.38, −0.23)**	0.15 (0.06, 0.23)	**0.23 (0.15, 0.31)**	**0.29 (0.22, 0.37)**	**0.04 (−0.05, 0.12)**
Cadence bout-to bout variability %	12.2±1.3	**0.35 (0.26, 0.42)**	−0.12 (−0.21, −0.04)	**−0.23 (−0.31, −0.14)**	0.11 (0.04, 0.19)	0.05 (−0.02, 0.13)	**0.24 (0.15, 0.32)**	**0.06 (−0.02, 0.14)**
Stride duration bout-to bout variability %	14.1±1.8	0.00 (−0.1, 0.09)	0.05 (−0.04, 0.13)	0.00 (−0.08, 0.09)	−0.01 (−0.10, 0.08)	−0.04 (−0.12, 0.04)	0.01 (−0.07, 0.10)	**−0.08 (−0.16, 0.00)**

Data are presented as median (interquartile range (IQR)), correlation coefficients (95% CI) or mean±SD. Bold type represents those for which convergent or divergent validity is suggested. 6MWD: 6-min walk distance; CAT: COPD Assessment Test; mMRC: modified Medical Research Council; FEV_1: forced expiratory volume in 1 s; QMVC: quadriceps maximum voluntary contraction; C-PPAC: Clinical visit PROactive Physical Activity in COPD; P90: 90th percentile. [#]: some variables have missing values: four values in walking speed bout-to-bout variability in longer (>30 s) walking bouts, and four values in stride length bout-to-bout variability in longer (>30 s) walking bouts.



https://doi.org/10.1183/23120541.00993-2025

FIGURE 1 Convergent validity with forced expiratory volume in 1 s % predicted across subgroups of age, sex, history of moderate-to-severe exacerbation in the past 12 months, and site (Mediterranean, Continental, Oceanic; see Methods). The dark grey areas represent *a priori* defined correlations; the light grey areas indicate exceeded correlations. WB: walking bout; P90: 90th percentile.

correlations for all related constructs except for QMVC torque, and were robust to stratifications by age group, sex and occurrence of exacerbations, consistent with previous research in COPD [27, 28]. They also exhibited good divergent and known-groups validity. Based on expert consensus, both walking duration and walking bout step count were deemed to exhibit construct validity.

Pattern

We assessed seven DMOs related to walking activity pattern. Four of these DMOs correspond to the number of walking bouts of different durations (overall, longer than 10 s, 30 s and 60 s). These are new parameters not previously tested in relation to other constructs. Longer walking bouts may identify outdoor walking and indicate both the ability and the behaviour to sustain longer walking bouts despite COPD symptomatology. These DMOs exhibited moderate-to-strong correlations with the 6-min walk distance, mMRC and FEV_1 % predicted, and weak correlations with CAT, C-PPAC difficulty and QMVC torque. However, walking bout duration bout-to-bout variability and walking bout duration correlation coefficients were low. Convergent validity results were found to be consistent across subgroups tested. Average walking bout duration and bout-to-bout variability matched four out of six hypotheses, although with weak-to-small correlations, potentially not supporting convergent validity. This is possibly related to most walking bouts being short due to behavioural patterns and living environments, making average walking bout duration less reflective of an individual's functional capacity and walking performance. All pattern DMOs supported divergent and known-groups validity. Expert consensus supported the construct validity of all pattern DMOs except for average walking bout duration and walking bout duration bout-to-bout variability. In addition, the number of walking bouts longer than 30 s appears to perform best and would be the preferred DMO within the walking activity pattern domain.

Gait DMOs

Pace

Real-world walking speed and stride length are two prominent metrics whose construct validity has not yet been assessed in people with COPD. Weak-to-strong correlation coefficients were observed, with most walking pace related DMOs meeting the expected ones, also in subgroup analyses, and all of them fulfilled the expected divergent and known-groups expectations. However, convergent, divergent, and known-groups validity of walking speed in shorter (10–30 s) walking bouts was not consistently met. There were consistently higher correlation coefficients between the DMOs in longer bouts and the related constructs, compared to shorter bouts. This is consistent with recent evidence suggesting that differences in DMOs between COPD and healthy counterparts are intensified during longer walking bouts [5], probably due to capacity limitations such as exertional breathlessness and peripheral muscle dysfunction being amplified during longer walking bouts [5]. Furthermore, shorter bouts likely reflect indoor walking activity. According to expert consensus, all pace DMOs, except walking speed and stride length in shorter (10–30 s) walking bouts, fulfilled construct validity. By examining the correlation coefficients, the P90 walking speed in longer (>30 s) walking bouts appears to be the preferred DMO to represent the pace domain.

Rhythm

Cadence and stride duration reflect the rhythmical and temporal walking patterns of an individual and emerging evidence has supported the clinical relevance of real-world cadence in COPD [6]. Our findings support convergent validity for average and P90 cadence, and stride duration in longer walking bouts, but not in all walking bouts. Furthermore, stride duration in all walking bouts did not provide known-groups validity. The C-PPAC score, a patient-reported outcome capturing symptoms experienced during physical activity and need for adaptations, showed low to medium correlations with DMOs. This probably reflects that DMOs specifically capture walking performance and may not reflect domains encompassed by the C-PPAC. In addition, QMVC torque, representing the maximum torque generated by the quadriceps muscles, may not be directly related to rhythmical gait patterns, and therefore showed no correlations with cadence, stride duration or their variability measures. Hence, like the pace DMOs, we suggest that rhythm DMOs are more appropriate and exhibit greater clinical validity when measured in longer bouts. As suggested by expert consensus, the walking rhythm DMOs exhibiting construct validity are cadence, P90 cadence, and stride duration in longer walking bouts. The preferred DMOs to represent rhythm seems to be P90 cadence in longer walking bouts.

https://doi.org/10.1183/23120541.00993-2025

TABLE 3 Expert consensus decisions about each digital mobility outcome (DMO) meeting construct validity or not

DMO	Individual evaluation results	Discussion	Consensus decision: meeting construct validity
Walking activity			
Amount			
Walking duration	100% in favour		Yes
Walking bout step count	100% in favour		Yes
Pattern			
Number of walking bouts	100% in favour		Yes
Number of walking bouts >10 s	100% in favour		Yes
Number of walking bouts >30 s	100% in favour		Yes
Number of walking bouts >60 s	100% in favour		Yes
Walking bout duration	66% against	• Correlations with CAT and FEV_1 weaker than expected correlations • Correlations with mMRC, a clinically important and potentially related construct, close to lower bound of expected correlations range • Correlations with C-PPAC difficulty close to lower bound of expected correlations range • Weaker correlations than other pattern DMOs	No
P90 walking bout duration	100% in favour		Yes
Walking bout duration bout-to-bout variability	66% in favour	• Only correlations with QMVC weaker than expected correlations • Construct validity was confirmed, but the expert group expressed caution in their interpretation, as clinical meaning and relevance of this DMO remains unclear	Yes
Gait			
Pace			
Walking speed in shorter (10–30 s) walking bouts	77% against	• Correlations with CAT, mMRC and QMVC torque weaker than expected correlations • Correlations with FEV_1 and C-PPAC difficulty close to lower bound of expected correlations range • Probably represents walking bouts performed indoors, which may reduce its clinical meaning	No
Walking speed in longer (>30 s) walking bouts	100% in favour		Yes
P90 walking speed in walking bout >10 s	100% in favour		Yes
P90 walking speed in longer (>30 s) walking bout	100% in favour		Yes
Stride length in shorter (10–30 s) walking bouts	77% against	• Correlations with CAT, FEV_1 and C-PPAC difficulty weaker than expected correlations • Correlations with mMRC and QMVC torque close to lower bound of expected correlations range • Likely represents walking bouts performed indoors, which may reduce its clinical meaning • Correlations for divergent validity relatively high	No
Stride length in longer (>30 s) walking bouts	88% in favour	• Some of the hypothesised related constructs may not have been ideal • Performed better than stride length in shorter (10–30 s) walking bouts	Yes

Continued

https://doi.org/10.1183/23120541.00993-2025

TABLE 3 Continued

DMO	Individual evaluation results	Discussion	Consensus decision: meeting construct validity
Rhythm			
Cadence in all walking bouts	66% against	• All correlations for convergent validity weaker than expected correlations • After joint revision of results all agreed to reject	No
Cadence in longer (>30 s) walking bouts	88% in favour	• Correlations with CAT close to lower bound of expected correlations range, and cadence probably not expected to correlate with QMVC torque • Other convergent, divergent and known-groups expectations were met	Yes
P90 cadence in longer (>30 s) walking bout	88% in favour	• Cadence likely not expected to correlate with QMVC torque • Other convergent, divergent and known-groups expectations were met • After joint revision of results all agreed to accept	Yes
Stride duration in all walking bouts	77% against	• All correlations for convergent validity weaker than expected correlations • After joint revision of results all agreed to reject	No
Stride duration in longer (>30 s) walking bouts	88% in favour	• Stride duration likely not expected to correlate with QMVC torque • Correlations with CAT and FEV_1 close to lower bound of expected correlations range • Divergent and known-groups expectations were met • Rest of correlations are good	Yes
Bout-to-bout variability			
Walking speed bout-to-bout variability in longer (>30 s) walking bouts	66% in favour	• Correlations with CAT and FEV_1 close to lower bound of expected correlations range • Other convergent, divergent and known-groups expectations were met • Construct validity is confirmed but the expert group expressed caution in their interpretation, as clinical meaning and relevance of this DMO remains unclear	Yes
Stride length bout-to-bout variability in longer (>30 s) walking bouts	66% in favour	• Correlations with CAT and FEV_1 close to lower bound of expected correlations range • Other convergent, divergent and known-groups expectations were met • Construct validity is confirmed but the expert group expressed caution in their interpretation, as clinical meaning and relevance of this DMO remains unclear	Yes
Cadence bout-to-bout variability	66% against	• Correlations with CAT, FEV_1 and QMVC torque weaker than expected correlations • Correlations with mMRC and C-PPAC difficulty close to lower bound of expected correlations range	No
Stride duration bout-to-bout variability	66% against	• All correlations for convergent validity weaker than expected correlations • After joint revision of results all agreed to reject	No

P90: 90th percentile; CAT: COPD Assessment Test; FEV_1: forced expiratory volume in 1 s; mMRC: modified Medical Research Council; C-PPAC: Clinical visit PROactive Physical Activity in COPD; QMVC: quadriceps maximum voluntary contraction.

Bout-to-bout variability

This domain provides information on the consistency of gait performance and has not been researched in people with COPD nor in other respiratory or cardiovascular conditions. Convergent validity was supported for walking speed and stride length variability, which was consistent across subgroups. Those DMOs also provided known-groups validity, with higher bout-to-bout variability values present in people with milder disease status and lower dyspnoea (supplementary figures S6–S8). These results suggest that people with less severe COPD can adjust their walking behaviour, *e.g.* to different surfaces as well as environmental and social factors, while people with more severe COPD may lack the capacity to adjust their walking patterns or simply move in an environment that requires less variability (indoors). Hence, according to expert consensus, walking speed and stride length bout-to-bout variability exhibited construct validity, but need further research in COPD to identify their clinical relevance and potential applications. Since the experts were unable to fully interpret the clinical meaning of bout-to-bout variability DMOs and the constructs that they represent, we suggest considering that this construct validity evidence be considered exploratory.

Implications

Our results support the potential use of DMOs for monitoring and management of people with COPD. A total of 17 Mobilise-D DMOs (pace, rhythm) relate to gait capacity and performance, while others (amount) reflect overall physical activity behaviour (table 3). This study constitutes the first published evidence of clinical validity for Mobilise-D DMOs [29] in COPD and provides regulatory-grade evidence for these digital biomarkers, aligning with the European Medicines Agency's recognition of their potential as monitoring biomarkers [30]. Further analysis of their predictive capacity for clinical events and establishment of their minimal clinically important difference is needed before recommending their use in real-world settings. These insights may guide personalised treatment and early detection. Potential clinical applications of DMOs include supporting disease management *via* objective, continuous outcome measures to help clinicians tailor pharmacological or nonpharmacological (rehabilitation) interventions and detect early signs of disease exacerbation. They may also enable early detection of health and functional decline, and facilitate remote monitoring. This includes monitoring outside of clinical visits, where changes in DMOs may serve as early indicators of deteriorating health status and prompt timely clinical assessment. However, additional clinical validation is essential before these tools can be routinely implemented. DMO-based monitoring may reduce the potential need for frequent clinic visits, which would be particularly beneficial for people with mobility challenges. The finding that 17 DMOs correlate with relevant constructs of functional and physical capacity, as well as health status in individuals with COPD, suggests that they may offer complementary insights into disease severity and health status.

At the research level, the present study is the first step in clinically validating DMOs in COPD. Important next steps include determining their predictive capacity for clinical events, and establishing their minimal clinically important difference, even for those that did not meet construct validity, before being definitively excluded as relevant DMOs for COPD. Finally, the sensitivity of DMOs following pharmacological and nonpharmacological interventions will need to be established through randomised controlled trials [31]. This would allow a holistic and comprehensive identification of the most clinically valid DMOs [29], and those that are suitable as outcome measures in clinical trials. After clinical validation is complete and the most robust DMOs are identified, these measures could be integrated as end-points in clinical trials evaluating nonpharmacological interventions, such as pulmonary rehabilitation, as well as pharmacological treatments. It will be important to ensure that the regulatory-grade evidence supporting these DMOs is extensively published and collected to facilitate their acceptance for as secondary or primary end-points.

Strengths and limitations

The multicentre design enhances generalisability across age, sex and disease severity. The rigorous protocol for data quality and pre-defined thresholds for valid wear time guarantees high data reliability, while the combination of *a priori* hypotheses, pilot study findings and expert consensus enforces the validity of the results. Construct validity was assessed using three types of statistical validity alongside clinical relevance from expert consensus, with the majority of DMOs (17 out of 24) meeting eight to 10 out of the 10 pre-defined hypotheses. While we acknowledge that some subjectivity is inherent in the expert judgement, the multidisciplinary nature of the panel and the inclusion of health practitioners adds methodological rigour and clinical relevance to the decision. This study presents a practical framework for assessing construct validity in digital mobility biomarkers by combining predefined hypotheses with carefully conducted expert consensus, grounded in existing regulatory frameworks [15–17]. Although the study population was primarily recruited from European urban settings, which may affect the absolute levels of DMOs and constructs, the clinical characteristics were comparable to other large European COPD cohorts, supporting generalisability [32–36]. Recruitment during the COVID-19 pandemic may have

influenced attendance, possibly favouring participants with milder disease. However, the construct validity is expected to remain similar in other settings, as any variation in the constructs would probably be reflected proportionally in the associated DMOs. Thus, the coefficients should be comparable, even if the levels differ across rural or non-European COPD populations. While the magnitude of correlation coefficients varied across geographical clusters (Mediterranean, Oceanic, Continental), the 95% confidence intervals overlapped, indicating consistent convergent validity across sites. We used typical constructs related to disease severity that can be measured in multicentre studies. Other criterion measures could have included overall energy expenditure, such as using doubly labelled water to comprehensively capture physical activity, although this would have not been appropriate since our focus was on walking activity only.

Conclusion

A total of 17 walking activity and gait DMOs, representing domains of amount, pattern, pace, rhythm and bout-to-bout variability, are objective and valid outcomes in COPD, as supported by convergent, divergent and known-groups validity after rigorous statistical testing and expert consensus evaluation. Specifically, all amount and most pattern DMOs demonstrate robust construct validity, while pace, rhythm and bout-to-bout variability DMOs show stronger clinical validity when derived from longer walking bouts. DMOs provide a seamless and cost-effective solution exhibiting great measurement and clinimetric properties and reflecting a wide range of clinical outcomes such as disease severity, functional capacity, health status and perception of physical activity. Finally, this study offers a template for rigorous construct validation of digital mobility biomarkers.

Provenance: Submitted article, peer reviewed.

Ethics statement: This study is part of the Mobilise-D Clinical Validation Study (ISRCTN 12051706), a multicentre observational cohort study. Ethical approval was obtained from all relevant local ethics committees across the participating European sites. The study was sponsored and coordinated by The Newcastle upon Tyne Hospitals National Health Service Foundation Trust, UK. Approval from ethics committees (EC) of all recruiting sites were obtained: Leuven (Belgium) (EC Research of University Hospitals Leuven (vote S64977)), Barcelona (Spain) (EC of Medical Research at Barcelona Hospital Clinic (vote HCB/2021/0445), EC of Medical Research at Parc del Salud (vote 2021/9797/I); EC of Research at University Hospital Germans Trias i Pujol (vote PI-21-093); EC of Research at Viladecans Hospital (vote PR129/21)), Newcastle (UK), London (UK) (London-Bloomsbury Research Ethics Committee (for both UK sites; vote 20/PR/0792)), Zurich (Switzerland) (Cantonal EC Zurich (vote 2021–00601)), Grosshansdorf (Germany) (EC of the Medical Association of Schleswig-Holstein (vote 023/21 I)), and Athens (Greece)(Sotiria Hospital Scientific Board (vote 1560/18-1-21)).

Conflict of interest: D. Megaritis reports support for the present study from Mobilise-D project, funded by the Innovative Medicines Initiative (IMI) 2 Joint Undertaking (JU) under grant agreement number 820820. M. Long and V. Lanfranchi were supported by the National Institute for Health and Care Research (NIHR) Sheffield Biomedical Research Centre (BRC) (NIHR203321); the views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. M. de las Heras was funded by European Union-NextGenerationEU, under the Program Investigo (INVESTIGO 2022, AGAUR- ref. BDNS 608313, file 2022 INV-1 00046 - Code 100046TC19). V. Alcaraz-Serrano, P. Alvarez, C. Becker, J. Braun, S. Buttery, N. Chynkiamis, L. Delgado-Ortiz, A. Frei, E. Gimeno-Santos, N.S. Hopkinson, A. Ionescu, C.P. Jansen, A. Kirsten, S. Koch, J. Lemos, B. Sharrack, D. Singleton and H. Watz have nothing to disclose. J. Buekers (FJC2021-046458-I) received funding from the Juan de la Cierva Formación financed by MICIU/AEI/10.13039/501100011033 and from the European Union NextGenerationEU/PRTR. B. Caulfield reports support for the present study from European Commission – IMI2 Programme – Mobilise-D project. A. Cereatti reports support for the present study from the Mobilise-D IMI project. S. Del Din and L. Rochester were also supported by the IDEA-FAST project that has received funding from the IMI2 JU under grant agreement number 853981; were also supported by the NIHR Newcastle BRC based at The Newcastle upon Tyne Hospital NHS Foundation Trust, Newcastle University, and the Cumbria, Northumberland and Tyne and Wear (CNTW) NHS Foundation Trust; and the NIHR/Wellcome Trust Clinical Research Facility infrastructure at Newcastle upon Tyne Hospitals NHS Foundation Trust; and the UK Research and Innovation Engineering and Physical Sciences Research Council (grant refs EP/X031012/1 and EP/X036146/1). S. Del Din reports consultancy activity with Hoffmann-La Roche Ltd. outside of this study. L. Rochester reports receiving consulting fees from the Michael J. Fox Foundation for serving on the Endpoints Advisory Committee; the content in this publication reflects the authors' view, and neither IMI nor the European Union, EFPIA, NHS, NIHR or any associated partners are responsible for any use that may be made of the information contained herein. H. Demeyer is a post-doctoral research fellow of the Flemish Research Foundation (FWO Flanders, #12ZW822N). A. Josa-Culleré acknowledges the Spanish Ministry of Science and Innovation through the Ayudas

para la Formación de Profesorado Universitario (FPU) 2020–2024 doctoral funding (FPU21/03336). K.E.J. Philip reports travel support from GSK (Travel Award Winner, 2024); nonpromotional speaker fees from Chiesi; and salary and research support from the National Heart and Lung Institute, Imperial College, through the Clinical Lecturer scheme. B. Vereijken reports funding from the IMI-JU2 under grant agreement number 820820. I. Vogiatzis is an associate editor of this journal. T. Troosters reports support for the present study from the Mobilise-D project, funded by the IMI 2 JU under grant agreement number 820820; consulting fees from Roche; and honoraria for lectures or presentations from AstraZeneca. J. Garcia-Aymerich reports support for the present study from Mobilise-D project, funded by the IMI 2 JU under grant agreement number 820820; ISGlobal acknowledges support from the grant CEX2023-0001290-S funded by MCIN/AEI/10.13039/501100011033, and support from the Generalitat de Catalunya through the CERCA Programme.

Support statement: This work was supported by the Mobilise-D project that has received funding from the Innovative Medicines Initiative (IMI) 2 Joint Undertaking (JU) under grant agreement number 820820. This JU receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations (EFPIA). Content in this publication reflects the authors' view and neither IMI nor the European Union, EFPIA or any associated partners are responsible for any use that may be made of the information contained herein. Funding information for this article has been deposited with the Open Funder Registry.

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