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Real-world gait study of Parkinson's disease using wearable sensors: A systematic review

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Abstract

Background: New technologies, such as wearable sensors, allow the quantitative assessment of gait alterations due to Parkinson's disease (PD) through Digital Mobility Outcomes (DMOs). These DMOs have the potential to complement traditional clinical assessments but must be relevant, reliable, and representative of the patient's overall condition. Real-world monitoring offers a valuable approach for this type of day-to-day evaluation of patients.
Objective: This systematic review has four primary aims: 1) To identify trends in protocol design for real-world gait monitoring using wearables in patients with PD. 2) To detail the analysis of inertial data and the computation of DMOs. 3) To summarize the clinical scales and symptoms studied. 4) To outline trends in the conclusions and limitations reported by authors in this field.
Methods: Three databases (MEDLINE via PubMed, Cochrane, and EMBASE) were systematically searched between September 1, 2013, and September 15, 2023. Eligibility criteria included studies involving adults with a PD diagnosis, the use of a wearable device with at least one accelerometer or gyroscope, and gait analysis conducted in real-world settings.
Results and Conclusion: Sixty-three studies were selected. Overall, wearables successfully provide clinically meaningful information on gait impairment in patients with PD. Stride speed as a DMO is well-established and clinically meaningful, while other metrics, such as stride length, stride duration, and cadence, show great promise for routine clinical practice and research. However, the lack of consensus on the methods of investigation and the small sample sizes remain significant barriers that must be addressed to facilitate broader adoption in clinical practice and research.

Keywords: IMUs, real-world, Parkinson, gait, digital features, DMOs, daily clinicometric

1 Background

Parkinson's disease (PD) is a chronic, progressive disabling disorder of the central nervous system. The World Health Organization reports that its prevalence has doubled in the last 25 years [1]. It is the second most common neurodegenerative disease according to the Global Burden of Disease Study [2]. PD is heterogeneous in clinical presentation and progression. It includes non-motor symptoms (sleep disturbance, cognitive impairment, fatigue, pain) and motor symptoms such as bradykinesia, rigidity, tremor and dyskinesia [3]. The International Parkinson and Movement Disorder Society sponsored a revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS), which is now the gold standard to measure the severity of PD [4]. It has four parts, partly completed by the patient and mostly scored by the clinician. Despite its advantages, several limitations of this scale are known. Subjectivity with inter-rater variability and non-linearity of scoring may underestimate the patient's symptomatology [5]. The snapshot view is also a limitation in this specific pathology, which has hour to hour variability and day to day fluctuations. While the limitations in reproducibility and quantification can be addressed through controlled, laboratory-based evaluations, the issue of fluctuations throughout the day and changes in the patient's real-life environment is still unresolved. There thus remains a need for an accurate quantification of real symptoms. In fact, the proportion of symptoms and their hourly variations, also due to drug intake, are only known by the patients and close relatives, and are roughly characterised in the scientific literature by estimates of a range [6]. Technology has proven its relevance over the past decades by gathering rich data that capture disease- and drug-related fluctuations in the complex condition of PD [7]. Wearable sensors are useful to measure sensitive and reliable ways of measuring an individual's symptoms. Specifically, inertial measurement units (IMUs) have been used for the study of locosensorimotricity and its variation in a controlled environment [8–10], and is currently emerging in real-world environments [11].

New challenges arise depending on the extent of use in each case. In a controlled environment, the experimenter manages the execution of the protocol by the participant and ensures the precise annotation of the inertial signal. On the other hand, with the experimenter's presence, the patient is subject to the white coat effect caused by the presence of medical personnel or environment, which influences the physiological measurements of the participants and their behavior [12]. Other psychological effects take place, such as the Hawthorne effect observed in people who are aware of participating in an experiment, which results in an increase in the motivation of the participants to perform the test and thus in the observed performance [13]. Furthermore, the spontaneous behavior of the patient as it would occur in their natural living environment is not observed.

On the other hand, real-world settings allow the observation of the patient's natural behavior within their ecological environment. However, adherence to protocols and the annotation of inertial signals in these environments are more complicated and less precise. There is a continuum of protocols between controlled and real-world environments. Some studies employ scripted activities in uncontrolled settings, while others use unscripted activities in controlled environments.

The lack of standardization of the protocols and the absence of unified methods of analysis—both in terms of the computation of the detection of gait events and their computational techniques—hinder the large-scale extraction of digital biomarkers for PD. Our study provides a synthesis aimed at identifying potential recurring and reliable themes.

1.1 Existing reviews

Seven previously published systematic reviews, shown in Table 1, have focused on gait studies using wearable sensors in real-world environments for PD, covering studies from 1995 to 2021, as illustrated in Figure 1. However, these reviews do not describe the raw inertial data analysis pipelines necessary for reproducing the study protocols [14–18]. Additionally, some reviews, such as Block et al.,[14] did not include studies published after 2010, as indicated in Figure 1. Another study by Rovini et al., [19] aimed to provide comprehensive scientific and technological information on wearable sensors for PD by analyzing 136 papers from 2007 to 2017. While they thoroughly described the definitions of the protocol, the analysis of the inertial data, and the clinical relevance, their review included only 14 papers on long-term home monitoring.

Fig. 1 Temporal Coverage of Seven Previous Systematic Reviews of Similar Topics

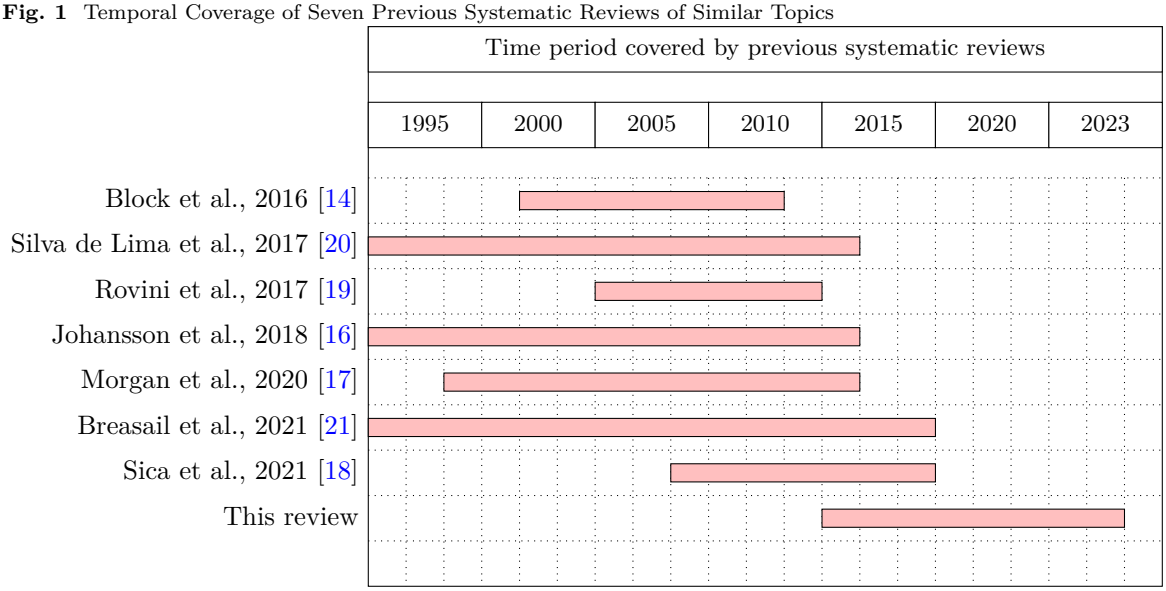


Table 1 Table of Topics Covered by Previous Systematic Reviews Compared to This Systematic Review

	[14]	[20]	[19]*	[16]	[17]	[21]	[18]	This review
Year of publication	2016	2017	2017	2018	2020	2021	2021	-
Number of included studies	137	27	136	56	65	28	24	63
Number of subjects	✓	✓	✓	x	✓	✓	✓	✓
Body area	✓	✓	✓	x	✓	✓	✓	✓
Number of wearables	x	✓	✓	x	✓	✓	✓	✓
Duration of recordings	✓	✓	✓	✓	✓	✓	✓	✓
Raw data analysis	x	x	✓	x	x	✓	x	✓
Detection of gait events	x	x	✓	x	x	✓	x	✓
Computation of digital features	✓	x	✓	x	✓	✓	✓	✓
Standard clinical correlation	x	✓	✓	✓	✓	✓	✓	✓
Description of studied symptoms	✓	✓	✓	✓	✓	✓	✓	✓
Description of results	✓	✓	✓	✓	✓	✓	✓	✓
Description of limits of study	✓	✓	✓	✓	✓	✓	✓	✓

* While they thoroughly described the definitions of the protocols, the analysis of the inertial data, and the clinical relevance, their review included only 14 papers on long-term home monitoring.

Table 1 summarizes all the reviews that have addressed key topics relevant to this paper: the use of wearable IMUs in real-world settings for patients with PD. It specifies whether these reviews addressed the main objectives of this review, namely, describing the protocol, analysis of the wearables' signals, and the clinical relevance of the computed gait features.

Each review takes a slightly different angle (see Table 1), except for Rovini et al. (2017) [19], which clearly describes the protocols and gait event detection in the inertial signal analysis. However, Rovini et al., included only 14 papers on long-term home monitoring. Our review, with four times as many articles, provides an updated perspective using the PRISMA method on the use of wearable sensors to study PD in real-world environments [14, 16–18, 20].

1.2 Scope of this review

As presented in Table 1 and Figure 1, there is a need to comprehensively update the literature to include recent studies on the subject, along with a precise description of the protocols and processing chains for inertial data. This systematic literature review aims to provide a detailed description of the protocols and inertial data computation methods used in real-world continuous monitoring with wearable sensors in patients with PD. The aim is to address the following four sets of research questions:

1. How are protocols designed in a real-world setting regarding the number and location of the wearable sensors, recording time per patient, and compliance tools?

2. How is the inertial signal analyzed: what raw data is analyzed, is gait recognition performed, and if so, how, and what gait features are computed and aggregated over the recording period?
3. Are the calculated gait features clinically relevant? Are specific symptoms being studied?
4. What are the results of these studies? What conclusions can be drawn about the aims of the study? What limitations do the authors describe?

1.3 Organization of this paper

Section 1 introduces this paper, reviews the relevant literature on similar topics 1.1, and outlines this study's scope and limitations 1.2. Section 2 details the methodology, including the search strategy 2.1, selection criteria 2.2, methods for data pooling and analysis 2.3, and risk of bias assessment 2.4. Section 3 presents the results, focusing on the studies' aims in 3.1, trends in real-world protocol design in 3.2, inertial signal analysis in 3.3, and the clinical relevance of the computed gait characteristics in 3.4. Section 3.5 presents a detailed synoptic table of twenty included studies, selected on the basis of their quality score and their transparency at each stage of the analysis. Section 4 offers an overall discussion, and then Section 5 addresses the study's main conclusions. Section 6 discusses its limitations.

2 Methodology

The literature search and analysis followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[22], which offer a transparent and standardized framework for conducting and reporting systematic reviews. The methods were established prior to conducting the review.

2.1 Search strategy

The systematic review protocol is registered in the International Prospective Register of Systematic Reviews (PROSPERO) under identification CRD42023452810. We searched the MEDLINE (via PubMed), Cochrane Central, and EMBASE databases to identify articles published between September 1st, 2013, and September 15th, 2023, that assessed real-world gait using wearables in individuals with PD.

The search strategy combined MeSH (Medical Subject Headings) terms and keywords related to PD ("Parkinson's Disease", "PD"), gait activity ("gait", "walk", "step"), quantitative motion analysis ("sensors", "IMU", "accelerometer", "gyroscope", "wearable", "motion analysis"), and the study setting ("real-world", "FLE", "remote monitoring", "daily living", "real-condition", "continuous home monitoring"). The full search equations are available in Supplementary Table A. We also reviewed the reference lists and bibliographies of the included studies for additional relevant articles.

2.2 Selection criteria

Studies were included if they involved adults clinically diagnosed with PD and assessed real-world gait using wearable devices containing at least one accelerometer and/or gyroscope. We excluded studies that:

- Did not focus on individuals with PD (population criterion),
- Did not assess walking specifically (gait criterion),
- Focused only on general physical activity (gait criterion),
- Used wearable sensors without at least one accelerometer and/or gyroscope (wearable criterion),
- Did not include free-living monitoring (ambulatory criterion).

After removing duplicate references, the review proceeded in two stages:

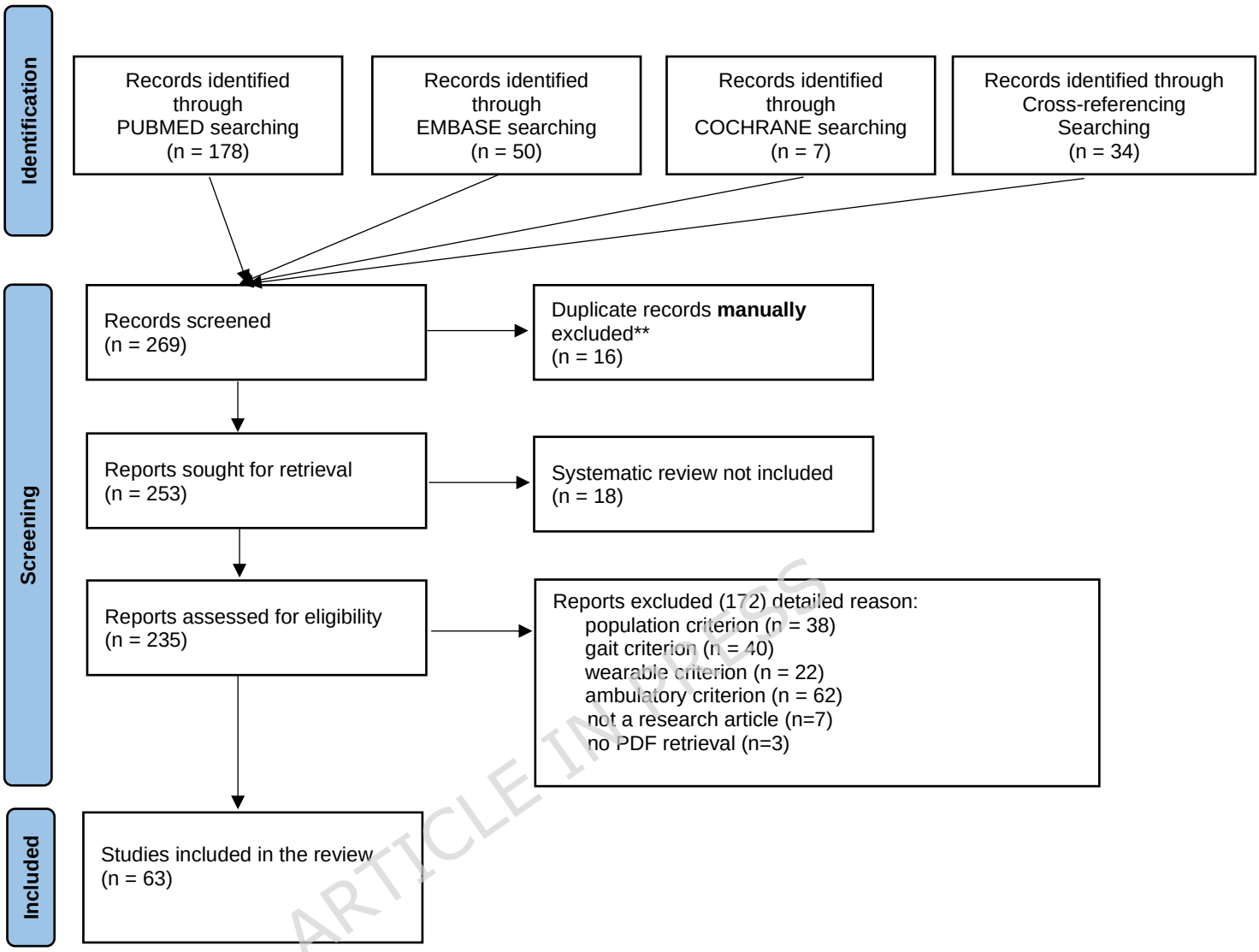
1. **Abstract Screening:** M.M. and D.R. screened the abstracts independently to identify studies focused on gait assessment using wearable devices in real-world environments for patients with PD, with disagreements resolved by consensus.
2. **Full-Text Screening and Eligibility Assessment:** Full-text studies were thoroughly reviewed. A study was included if it involved a patient with PD and used wearables (including smartphones) with accelerometers and/or gyroscopes to assess gait in real-world, unsupervised environments, as opposed to simulated settings.

2.3 Data extraction

A full evaluation of the included studies was performed. We adapted the "Table of data elements to be extracted" from Polhemus et al., 2020 [23], modified for our review as follows:

- **Protocol design:** Number and location of wearable sensors, recording duration per patient, and compliance tools.
- **Inertial signal analysis:** Type of data analyzed, walking bout detection, gait detection methods, and computed gait features aggregated over the recording period.
- **Clinical relevance:** Evaluation of the clinical relevance of the computed gait features, and whether specific PD symptoms were targeted.
- **Conclusions:** Main findings, conclusions regarding the study's aims, and limitations noted by the authors.

Fig. 2 PRISMA Flow Chart Illustrating the Selection Process for the 63 Included Studies



2.4 Assessing risk of bias

The assessment of the quality of each study included in this systematic review was conducted using a 20-item grid adapted from Hubble (2015) [24], originally developed to appraise the methodological rigor of studies using wearable sensors for gait analysis. This tool was chosen for its relevance to real-world mobility monitoring, capturing both technical (e.g., device specification, signal processing) and clinical (e.g., population description, outcome validity) aspects of the quality of the study. The full grid and scoring criteria are available in the supporting information in Appendix B. Sixteen of the criteria in the quality assessment tool were assigned a score of one point if the criterion was met or zero if the criterion was not met. If it was not possible or if it was unreasonably difficult for the assessors to determine whether the information required for a particular criterion had been provided by the authors, a score of zero was given for that criterion. Three items were assessed on a 2-point scale, with the study receiving 2 points if the criteria were clearly described, 1 point if they were partially described, and 0 points if they were not described.

After each paper was assessed in terms of these criteria, the scores were summed and divided by the maximum possible total points to yield a final score representing the percentage of total possible points earned. This percentage was used to evaluate the overall quality of the study, using quartiles to classify the methodological quality of the article as either very low ($<25\%$), low ($\geq 25\%$ but $<50\%$), moderate ($\geq 50\%$ but $<75\%$), or high ($\geq 75\%$).

Only 5% (3/63) of the studies are of low quality, 3% (2/63) did not permit an evaluation, 57% (36/63) are of moderate quality, and 35% (22/63) are of high quality. This shows that the vast majority of studies (92%) are of at least moderate quality, making them appropriate for interpretation and inclusion in the systematic review. The median quality score is 19/25, corresponding to high quality, with an interquartile range of 4. Most study quality scores are closely clustered around the median, indicating that the assesment is consistent.

The most common biases are related to the assessment of the power and external validity of the studies. This reflects the challenges of patient recruitment and the representativeness of the included patients compared to the overall population, which affects the generalizability of the study's results to the wider population.

3 Results

In the following section, the 63 included studies are analyzed according to the research questions of the present review. Thus, Section 3.1 describes the included studies, and Section 3.2 outlines the protocols defined in those studies. The analysis pipeline is described in Section 3.3, clinical references are discussed in Section 3.4, and Section 3.5 contains a summary of a selection of 20 articles.

3.1 Design and aims of the studies

The studies included in this review had diverse objectives, ranging from testing the algorithms of wearable systems against reference system computed algorithms (referred to as analytical validation), to clinical exploration of the computed DMOs, and the use of DMOs as evaluation criteria in interventional studies. We observed two study designs: observational and interventional. Additionally, three main categories of study aims have been identified, corresponding to the objectives mentioned: wearable system analytical validation, exploration of DMOs, and the use of DMOs as evaluation criteria.

3.1.1 Clinical study design

Clinical trial design involves the formulation of trials, experiments, and observational studies in medical, clinical, and other types of research (e.g., epidemiological) involving humans [25]. 90% (57/63) of the included studies are observational [15, 20, 26–80], encompassing cohort studies and cross-sectional studies. The remaining 10% (6/63) are interventional studies [81–86].

3.1.2 Aims

The purpose of each study included in this review has implications for the design of the protocol and the analysis of the inertial signals. Inspired by Polhemus et al., 2020 [23], we identified three categories of purposes into which the 63 studies fall:

1. Analytical validation of the wearable system: this involves testing a new method proposed by the authors against an existing reference method to compute DMOs 32% (20/63) [29, 34, 35, 39–41, 43, 50, 53, 59, 61, 65, 66, 69, 70, 73–75, 78, 87]
2. Relationships between DMOs as clinical biomarker and clinically-relevant measures 52% (33/63) [26–28, 30, 31, 36, 38, 42, 44–49, 51, 52, 54–56, 58, 63, 64, 67, 68, 71, 72, 76, 77, 79, 80, 83–85].
3. The use of DMOs as an evaluation criteria in clinical trials 16% (10/63) [15, 32, 33, 37, 57, 60, 62, 81, 82, 86]

Overall, the development and exploration of DMOs in clinical research appear to be in its early stages, with a predominance of observational studies and a focus on analytical validation and exploration of DMOs.

3.2 Research question 1: Description of the protocols

This section presents various definitions of protocols, including determining the sample size (3.2.1), descriptions of the wearable systems used and their locations on the body (3.2.2), and the setup and monitoring of real-world recording environments (3.2.3).

3.2.1 Determination of the Sample size

The sample size is crucial for the reliability of the results of a study and varies depending on the study's purpose. Studies with fewer than 100 subjects are the most common, constituting 70% (44/63) of the reviewed literature [15, 26, 28, 31–33, 35, 37–40, 42, 43, 45, 46, 48–54, 57, 59–61, 64–66, 68, 69, 73–85]. Notably, 27% (17/63) of the studies include fewer than 30 subjects [31, 40, 43, 45, 46, 52, 59, 61, 64, 65, 73–75, 77, 78, 80, 85]. The distribution of sample sizes depends on the aim of the study, as shown in Figure 3. Smaller cohorts are more frequently observed in studies evaluating wearable systems. Two studies involving over 1000 patients stand out. Omberg et al., (2022) [44] aim to evaluate the use of health sensors through a smartphone application that patients can download. Mikolaizak et al., (2022) [36] conducted a multicenter study on the clinical validity of DMOs in patients with mobility impairments.

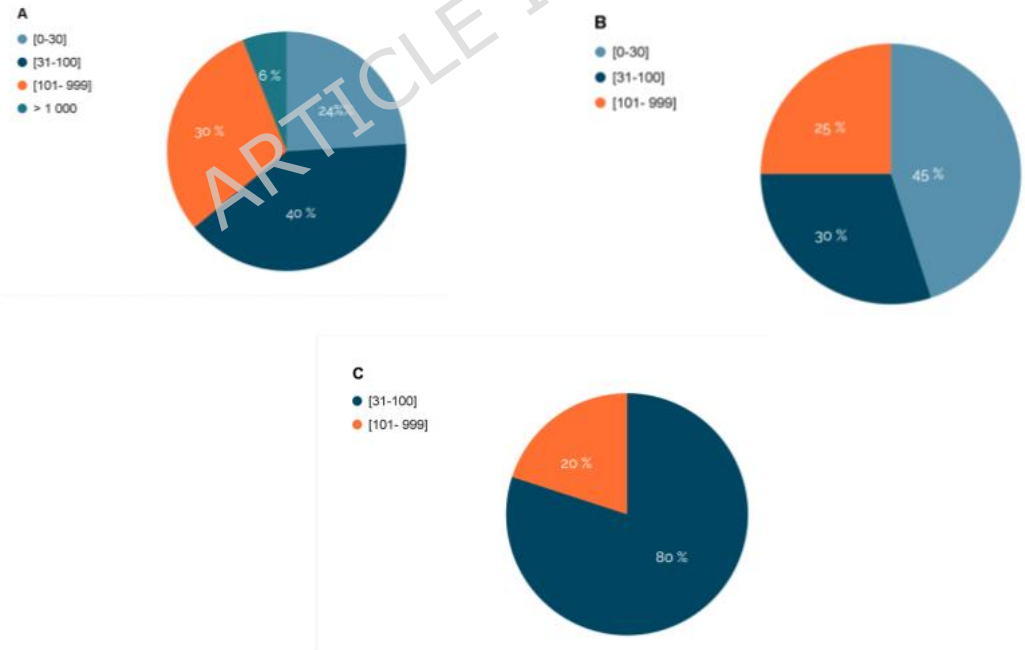


Fig. 3 Partitioning of study sample sizes according to their respective aims. A: Studies (33) investigating the relationship between DMOs and clinical measures. B: Studies (20) performing analytical validation of the wearable system. C: Studies (10) using DMOs for assessment.

3.2.2 Wearable system

A wearable system consists of sensors, including IMUs (accelerometers, gyroscopes, magnetometers, barometers), placed in various regions of the body to record movement. Some wearable systems are commercial technologies, such as smartphones that already include IMUs, while others are custom-made wearable systems connected to additional monitoring devices, such as pressure sensors in insoles. The placement of the sensors depends on the protocols and objectives, as shown in Figure 4. Some systems are commercially available and well-known, while others are custom-made by research teams, as illustrated in Table 2. Beyond the technological characteristics of the devices, the placement of the sensors on specific segments of the body carries significant methodological implications, as it directly determines the type and precision of the gait parameters that can be extracted. Likewise, it can also influence the patient's adherence, particularly in real-world or long-duration monitoring contexts.

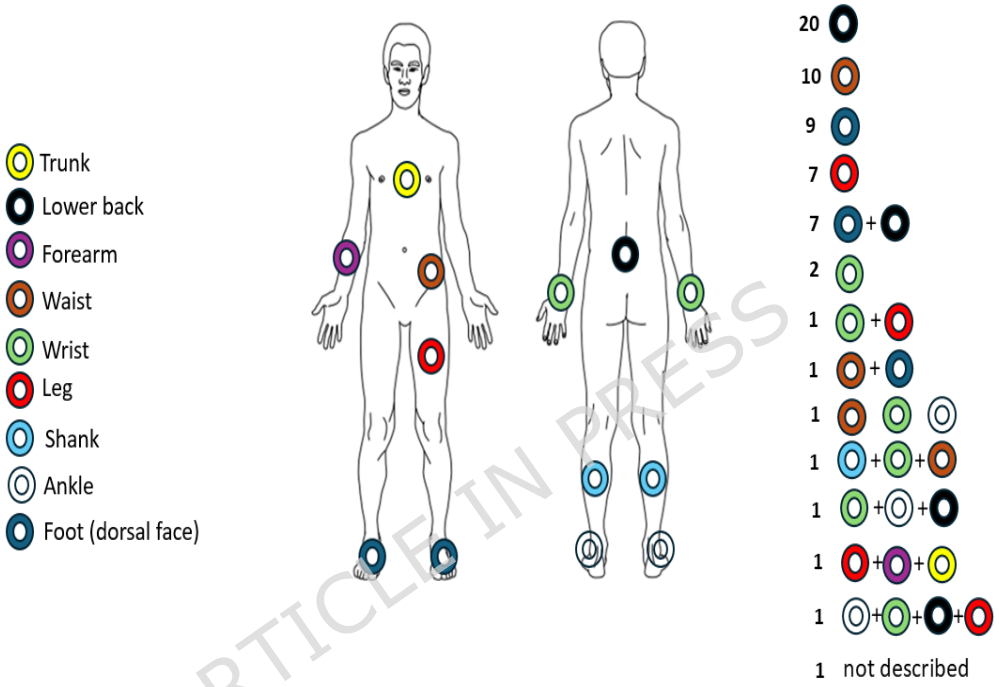


Fig. 4 Wearable Sensors Placement (IMUs, Accelerometers, Gyroscopes): Each colored circle represents a possible location of a wearable device. On the right, the configurations are shown, with the number in front indicating how many studies used each configuration.

The most common sampling frequency, used in 63% (40/63) of the studies, ranges between 100 and 150 Hz [15, 26, 27, 29, 30, 35, 36, 38–41, 43–49, 51, 52, 54, 56, 57, 60, 61, 63, 64, 67–70, 72, 76, 77, 79–82, 84, 86]. The lowest frequency found was in Lord et al., [71], where they used a 10 Hz sampling frequency. Notably, 14% (9/63) [31, 33, 34, 53, 58, 65, 73, 75, 83] of the studies do not specify the sampling settings used. Here, as shown in Figure 4, there is no strict consensus on the location of the wearable on the body. 22% (14/63) of the studies employ multiple sensor placement sites, reflecting a balance between data quality and patient convenience in real-world environments [30, 31, 36, 42, 48–51, 54, 58, 64, 65, 80, 82]. Nevertheless, the lower back appears to be a preferred location, used in 32% (20/63), due to its balance between gait events detection and patient practicality [26, 27, 29, 39, 41, 52, 56, 60, 61, 63, 67–70, 72, 76, 79, 81, 84, 86].

Concerning the type of wearable sensor, similarly, there is no marked consensus, which vary in brand as shown in Table 2. However, a notable trend is the use of connected everyday technology tools, such as smartphones and smartwatches, to integrate data recording into real-world settings.

Wearable Device Names	*Type of Sensors*	*Battery Life*	*Storage*	*No. of Studies*	*Weigth*	*Raw Data Recovery*	*Sampling Frequency*
Axivity: AX3®	accelerometers	14 days at 100 Hz	512 MB	11	11g	yes	12.5–100 Hz
Smartphone	connected device including IMU	˜10–15 hours	4 GB	9	130–250 g	no	10–500 HZ
McRoberts: DynaPort Hybdrid system®	IMU	10–20 hours	8–16 GB	9	50 g	yes	50–1000 HZ
Not specified	IMU	UNK	UNK	8	UNK	UNK	UNK
APDM: Opal®	IMU	16–24 hours	16 GB	6	32 g	yes	50–200 HZ
Actigraph®: GT3X	accelerometers	25 days	16 GB	4	25 g	yes	1–100 HZ
APDM: Mobile Gaitlab®	IMU	16–24 hours	16 GB	4	32 g	yes	50–200 HZ
Gait Up: Physilog®	IMU	10–14 hours	8 GB	3	25–30 g	yes	50–100 HZ
Fitbit®watch	connected device including IMU	˜10 days	2.5 Go	2	˜30 g	no	25–100 HZ
Axivity: AX6®	accelerometers	14 days at 100 Hz	512 MB	1	11 g	yes	0.25–3200 Hz
PAL Technologies: ActivPAL®	accelerometers	7 days	512 MB	1	15 g	yes	20 Hz
MC10: BioStamp®	accelerometers	4–7 days	512 MB	1	10–15 g	yes	10–1000 Hz
PD Monitor Ltd.: PD Monitor®	IMU	4–7 days	8 GB	1	20–30 g	yes	50–2000 Hz
APDM: PERFORM System®	IMU	8–16 hours	16 GB	1	50–60 g	yes	50–200 Hz
Gait Up: INDIP System®	IMU	8–12 hours	16 GB	1	30–40 g	yes	50–2000 Hz
APDM: Prototype System	IMU	8–16 hours	16 GB	1	30–60 g	yes	50–2000 Hz

Table 2 Details of the wearable sensors used according to the manufacturer. *IMU (Inertial Measurement Unit), which includes at least an accelerometer or a gyroscope.* Detailed Micro-Electro-Mechanical Systems (MEMS) parameters (bias, drift, misalignment) are not disclosed by most clinical device manufacturers. For Axivity devices, manufacturer specifications are available and provide the following values: for AX6, bias ±70 mg, drift ±1.0 mg/°C, and ∼ 1% misalignment for the accelerometer; bias ±3 °/s, drift 0.05 °/s/°C, and ∼ 2% misalignment for the gyroscope. For AX3, bias ±40 mg, drift ±1.2 mg/°C, and ±1% misalignment.

3.2.3 Environment

The definition of the environment is essential for the analysis of human movement in uncontrolled settings. It includes details about the physical environment in which the recording takes place, the duration of the recording period, and the tools used to verify patient compliance.

A real-world setting is defined as 'unsupervised, uncontrolled, and unstandardized free-living,' according to Kluge et al., (2021) [88]. This is in contrast to laboratory-based environments, which are fully controlled and observed, as well as semi-controlled tests, which include supervision even when the patient is allowed to act freely.

Overall, 54% (34/63) of the studies were recorded only in a real environment, defined as uncontrolled and unscripted activities [26, 29, 31–33, 36, 37, 40, 46, 48–52, 59–62, 65–68, 72–76, 78–80, 83, 84, 86, 87]. Thirty-three percent (21/63) include some recording in a controlled environment, characterized by scripted activities in a closed setting [15, 27, 28, 34, 37, 39, 40, 42, 43, 51, 55–57, 63, 69–71, 77, 81, 82, 85].

Ten percent (6/63), in addition to continuous real-world recording, set up a semi-controlled environment involving specified tasks in an uncontrolled setting [43–45, 47, 53, 64]. Additionally, 3% (2/63) of the studies use controlled, semi-controlled, and real-world recordings [30, 41].

A total of 40% (25/63) of the studies used a 7-day recording period [26, 27, 36, 39–41, 48, 49, 51, 52, 54, 56, 61, 64, 66, 70–72, 76, 80–84, 86], while 35% (22/63) employed a period between 1 and 6 days [15, 28–31, 34, 37, 42, 46, 50, 55, 57, 59, 63, 65, 67–69, 73, 77, 79, 80]. Thirteen percent (8/63) of the studies recorded between seven days and one month [32, 33, 35, 38, 43, 53, 58, 62]. Additionally, 5% (3/63) of the studies recorded data for more than one month [44, 45, 47], and one study extended the recording period to more than 3 months [20]. Six percent (4/63) of the studies did not precised recording period duration [74, 75, 78, 85]. Overall, the most frequent recording period length was one week.

Overall, 46% (29/63) of the studies used compliance check methods [15, 26, 28, 32, 33, 35–38, 40–47, 50, 53, 55, 58, 59, 61, 65, 66, 73, 79, 84, 87]. Mobile applications were used in 22% (14/63) of the studies [28, 33, 37, 38, 41, 43–45, 47, 50, 53, 58, 84, 87], patient-kept diaries were employed in 14% (9/63) of the studies [36, 40, 42, 46, 55, 61, 66, 73, 79], 6% (4/63) combined two compliance check methods (diary and application [78] or diary and phone call [26, 32, 65]), only one study used only phone calls [35], and one study used video recording [15]. Notably, more than half of the studies (54%, 34/63) did not detail or include a compliance check on the use of wearable sensors by participants during real-world recordings [27, 29–31, 34, 39, 48, 49, 51, 52, 54, 56, 57, 60, 62–64, 68–72, 74–83, 85, 86].

Protocol design is fundamental to ensuring data quality and achieving the specific objectives of a study. Overall, there is a tendency to implement small to very-small cohorts, with no consensus on the specific wearable sensors or sample size calculation. However, connected devices, such as smartphones and smartwatches, are increasingly being used in scientific protocols.

3.3 Research question 2: inertial analysis

The stages of signal analysis in the context of inertial sensors for gait studies in patients with PD typically involve the following key steps:

1. Analysis of Raw Inertial Data: this initial stage involves low level processing the raw data obtained from accelerometers and gyroscopes. Techniques such as filtering, segmentation, and alignment may be applied to prepare the data for further analysis.
2. Gait events detection: gait events detection is crucial for identifying specific events in the gait cycle, such as heel strikes (initial contacts) and toe-offs (final contacts). Methods used for automatic gait events detection include threshold-based approaches, machine learning algorithms (e.g., Random Forest, Support Vector Machine), and heuristic methods tailored to detect gait-specific events.
3. Feature Extraction from Inertial Signals: features are calculated from the inertial signals to characterize various aspects of gait. These features can be categorized into time-domain, frequency-domain, and other domains (e.g. wavelet transform). Common features include gait parameters such as stride length, cadence, variability metrics, and symmetry indices.

3.3.1 Raw signal

Only 48% of the included studies used raw accelerometer data to compute gait characteristics. Thirty five percent of the studies use raw accelerometer and angular velocity data. Height percent of the studies did not describe which raw data were analysed (Figure 5).

3.3.2 Gait events detection

Gait event detection typically involves peak detection, identifying key moments in the gait cycle. The two primary moments detected are the initial contact (IC), corresponding to heel strike, and the final contact (FC), corresponding to toe-off.

In 33% (21/63) of the studies, activity detection followed by gait event detection was performed on the raw inertial signal [28, 41, 42, 47, 50–52, 54–57, 59–61, 64, 66, 77, 79, 86]. Activity detection can be performed manually or using machine learning classifiers, such as Random Forest, Support Vector Machine, and Decision Trees.

Only activity detection was performed in 17% (11/63) of the studies [31, 48, 53, 63, 65, 71, 74, 75, 78, 80, 87].

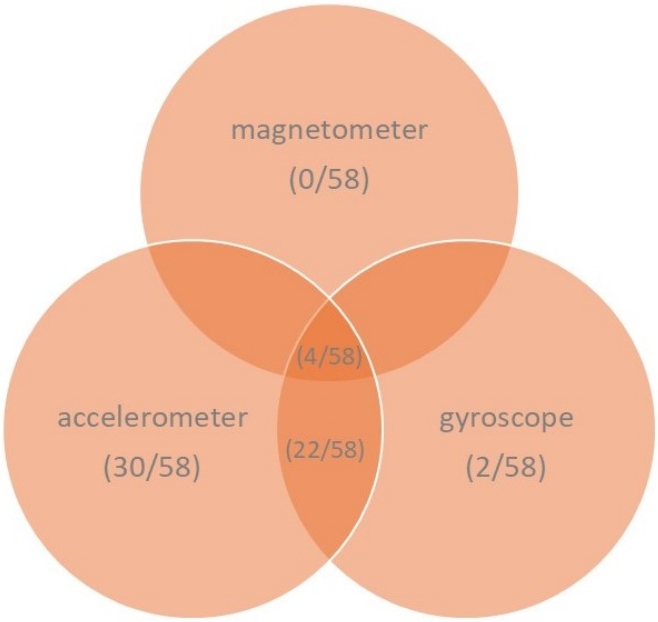


Fig. 5 Distribution of Raw Signal Types Used for Gait Analysis in the 58 Studies Reporting Raw Signal Analysis: This describes the repartition of different raw signal types used in gait analysis across the 58 studies that specified the raw signal analyzed.

Gait event detection analysis was performed in 37% (23/63) of the studies [15, 26, 27, 29, 30, 34, 35, 38–40, 43–46, 49, 67–70, 76, 81, 84, 85]. In this group, the majority (87%, 20/23) detected gait events by identifying threshold crossings in accelerometer and gyroscope signals, corresponding to key phases of the gait cycle, such as heel strike (IC) and toe-off (FC). Gait event detection was applied either across the entire signal or within specific segments corresponding to gait phases [26, 27, 29, 30, 34, 38, 39, 44–46, 49, 67–70, 76, 81, 84, 85].

Evers et al. [15] performed threshold detection and used manual annotation of inertial data to detect activities and strides recorded in real-world environments using video cameras.

Some studies (13%, 3/23) used gait event detection with a pattern-matching approach, such as Dynamic Time Warping methods [35, 40, 43].

Seven studies (11%, 7/63) did not specify the methods used for gait event detection or activity detection [33, 36, 37, 58, 62, 82, 83].

One study performed spectral analysis on the inertial signal [32].

3.3.3 Walking Bouts and DMOs

In 49% (31/63) of the studies, the detection of bouts of walking (WB) detection was performed before computing the DMOs [15, 27, 29, 30, 34, 38–41, 46, 48–52, 54, 56, 59–62, 64, 67, 71, 72, 76, 77, 79, 80, 85, 87]. There are diverse definitions and selections of WBs. Some studies defined WBs based only on spatial criteria, which must include a certain number of strides [27, 29, 34, 39, 41, 50]. Others used only temporal criteria, defining WBs solely by their duration [15, 56, 60, 62, 64, 71, 79]. Some studies combined spatial and temporal criteria, requiring a minimum number of steps and a minimum or maximum duration of the episode [30, 38, 59, 76, 77, 79, 85]. Furthermore, certain studies considered a minimum time interval between two successive WBs to avoid counting them as a single episode [27, 40, 46, 48, 49, 51, 54, 61, 72, 76, 80]. Beyond this segmentation into WBs, there were studies that analyzed only specific categories of WBs by filtering based on a minimum or maximum duration [27, 46, 52, 86].

The DMOs were computed from the inertial signal using different types of features. Time-domain features computed from the inertial signal were the ones mainly used, as shown in Tables **??** and 4. However, studies also used frequency-domain features [47, 56, 79] or wavelet-domain features [47].

Table 3 List of DMOs computed in the 63 included studies. Only DMOs reported in ≥2 studies are shown. Columns indicate whether each DMO differentiates patients vs healthy or disease severity

Category	DMO	Number of studies	Patients vs Healthy	Severity
Time domain features	Step or stride velocity	17 (27%)	✓[71]	✓[57]
	Step or stride length	11 (17%)	✓[51]	✓[57]
	Stride duration	11 (17%)		
	Cadence	10 (16%)		
	Number of steps or strides per day	8 (13%)	✓[42]	
	Turn duration	5 (8%)	✓[64]	
	Gait stance phase duration	5 (8%)		
	Variability of stride duration	4 (6%)		✓[57]
	Double support time	4 (6%)		
	Duration of gait swing phase	4 (6%)		
	Step asymmetry	3 (5%)		
	Number of steps to complete a turn	3 (5%)		
	Variability of gait swing time	3 (5%)	✓[49]	
	Pitch at Initial Contact phase	3 (5%)	✓[54]	
	WB duration	2 (3%)	✓[71]	
	WB length distribution	2 (3%)		
	Number of WB per day	2 (3%)	✓[71]	
	Turn angle amplitude	2 (3%)	✓[37, 54]	✓[64]
	Turn peak velocity	2 (3%)	✓[63]	
	Variability of gait double support time phase	2 (3%)		
	Variability of gait swing time phase	2 (3%)	✓[51]	
	Variability of gait stance time phase	2 (3%)		
	Asymmetry of gait stance time phase	2 (3%)		
	Pitch at final contact phase	2 (3%)		
Frequency domain feature	Width dominant peak	2 (3%)		
Symptom feature	Freezing of Gait	5 (8%)		
	Bradykinesia / Dyskinesia	3 (5%)		

3.4 Research question 3: Clinical relevance

This section provides a description of the scales measuring the severity of the condition, balance, falls, and health-related quality of life used in relation to DMOs, and their prevalence in the studies included in this review. It includes a subsection detailing the gait events associated with PD symptoms that were specifically assessed in some of the reviewed studies. Additionally, it examines trends in the motor scales and symptoms analyzed to investigate the clinical meaningfulness of the studied DMOs.

3.4.1 Clinical scale

Standard scales measure the severity of a patient's disease at a precise point in time. It consists of patient-reported outcomes (PRO), which take the form of questionnaires completed by patient about the perception of their condition at a given time. The clinically reported outcome (CRO) score is an assessment made by a clinician.

Among CROs, the MDS-UPDRS-III scale is the scale most commonly found, in 87 % (55/63) of the studies, [15, 27–32, 34–57, 59–65, 67–71, 74, 76, 77, 79–82, 84–87]. Next in frequency is the Hoehn and Yahr scale, which is also a standard assessment of PD, found in 57% (36/63) of the included studies [15, 26, 29–32, 34, 37–40, 42, 43, 45, 46, 54, 56, 57, 61–63, 66, 69, 71, 73–81, 83, 85, 86]. The levodopa equivalent daily dose (LEDD) is measured and reported in 19% (12/63) of the studies [15, 26, 32, 39, 52, 57, 71, 76, 79, 81, 83, 84]. A PRO commonly found is a self-administered questionnaire, such as the New Freezing Of Gait Questionary (NFoG-Q), which was used in 13% (8/63) of the studies [26, 36, 60, 67, 68, 79–81]. Global standard scales are also important to assess the cognitive function of the participants in a clinical trial, such as the Montreal Cognitive Assessment (MoCA), which was used in 16% (10/63) of the studies [26, 34, 36, 37, 39, 41, 42, 68, 79, 81]. The Mini Mental State Examination (MMSE) was also used in 14% (9/63) of the studies [55, 63, 66, 67, 70, 71, 79, 80, 83]. Standard physical evaluations are also found, such as the Activities specific balance confidence Scale (ABC), found in 6% (4/63) of the studies [39, 61, 80, 82], or the Berg Balance Scale (BBS), which evaluate the static and dynamic balance of the patient, used in three studies [63, 69, 79].

With 87% of the studies using the MDS-UPDRS-III and 56% the Hoehn and Yahr scales specifically for PD, we observe that the majority tendency is to use these scales to assess patients with PD. Only one study did not use either of these scales. [33]

3.4.2 Mobility event studied

Seventeen percent of the studies investigated the FoG symptom, which is manifested as an inability to initiate or maintain walking [36, 47, 48, 65, 74, 75, 78–80, 83, 84]. The clinical reference data collected was the NFoG-Q, correlated with the DMOs. Some studies compared quantitative and qualitative gait parameters between FoG and non-FoG patient groups [79, 83], while others, such as Mancini et al., (2018) [80], calculated more specific FoG-related metrics, such as the average time spent in freezing per patient.

Other PD specific symptoms studied, such as bradykinesia—characterized by slowness and reduced amplitude of movement—and dyskinesia, which involves involuntary movements, are less clearly represented in the calculation of the metrics [31, 50, 58, 65, 73, 82].

3.5 Research question 4: Authors' conclusions

This section contains a summary table of 20 studies included in the systematic review. These studies were selected based on their bias assessment score, as well as the transparency of their protocols and the analysis process. It provides detailed information on the protocols, processing of the inertial data, calculation and aggregation of the DMOs, as well as the main results of the study.

Year	Author	Aim	Cohort Size	Wearable (location)	Duration	DMOs	Aggregation	Key Results
2022	Omberg et al., [45]	Evaluate mobile phones for real-world evidence collection within a remote study	1414	Smartphone (Pocket)	> 1 month	~ 100 features combined in clinical score	IQR	Correlation between combined DMOs scores and global UPDRS score
2021	Mancini et al., [49]	Characterize FoG in daily life	48	Opal® (Feet + Lower back)	7 days	Stride velocity Foot pitch at initial contact	Mean of all RP	Higher FoG time, lower turn angle and pitch angle in FoG group
	Atrsaei et al., [78]	Compare clinical versus home gait assessments	27	Physilog® (Feet)	1 day	Stride velocity	Mean, SD, median, IQR	Similar gait speeds in clinical and home settings
	Adams et al., [43]	Examine activity profile, gait, tremor in clinic and real-world	20	BioStampRC® (Legs + Forearm + Trunk)	3 days	Steps/day Step length Step velocity Step duration	Median, IQR	PD group had similar step duration, length, speed, but poorer coordination than control group
2020	Shaha et al., [50,52]	Better understanding gait during daily life in neurological populations	16	IMUs Prototype (Feet + Lower back)	7 days	Cadence Double support Elevation at mid swing Stride velocity Foot strike angle Toe off angle Stride duration Swing duration	Mean, SD	Significant lower stride velocity and higher foot strike angle in real-world recording between PD and control group
		To determine which DMOs discriminate mobility in people with PD from control group.	29	Opal® (Feet + Lower back)	7 days	43 DMOs	Mean, CV	DMOs such as turn angle, terminal swing variability, swing time variability, single limb support variability, and pitch at initial contact variability, were more discriminative for PD than for control group when compared to traditional measures, such as the number of strides per hour
	Del Din et al., [87]	To investigate the relationship between walking activity and fall rates before and after an exercise program.	128	Axivity AX3® (Lower back)	7 days	Walking time per day Percentage of walking time Number of steps per day Number of WBs per day Falls Rate and Activity Index	Mean, SD Median, IQR	The PD group had less walking time, fewer walking bouts, and fewer steps per day compared to the control group. The PD group also had higher fall rates and activity scores than the control group. After the exercise program, the PD group showed a decrease in fall rates and activity scores
2019	Del Din et al., [73]	To explore generic and specific associations in free-living gait in fallers and non-fallers with and without PD	155			Walking time per day Number of WBs WBs patterns	Mean across each WBs then across all WBs	Fallers walked in shorter, more consistent bouts and spent less time walking overall. They had fewer long WBs (longer than 60 or 120 seconds), walked more slowly, and took shorter, less variable steps. PD non-fallers walked more

								slowly and had longer step, swing, and stance times compared to control group
	Galperin et al., [57]	Evaluate the relationship between PD motor symptom severity and metrics based on the laboratory-based assessment of mobility and the daily-living assessment of mobility	125	Axivity AX3® (Lower back)	7 days	Number of steps Number of WBs Pace Step Length Gait symmetry Step regularity Gait variability across WBs Peak amplitude	Mean across each WBs then across all WBs	Total daily physical activity was not strongly related to the UPDRS score or lab-based assessments of balance and gait. However, gait speed showed a moderate correlation with the UPDRS-III score
2018	Lipsmeier et al., [59]	Assess the feasibility, reliability, and validity of smartphone-based digital biomarkers of PD in a clinical trial setting	44	Smartphone (Pocket)	6 days	Turn speed Gait-related activity percentage	Mean of all RP	Both features significantly differentiated PD from control group
	Mancini et al., [61]	To examine if turning in the daily living environment is more impaired in PD patients with FoG compared to those without, and to explore the relationship between turning and disease severity	94	DynaPort® (Lower back)	3 days	Number of turns per 30 minutes Turn angle amplitude Turn duration Peak turn velocity Turn jerkiness	Mean, CV	The quantity of turns was similar between freezers and non-freezers. Quality of turns differed: freezers showed significantly higher mean jerkiness and higher mean and variability (CV) of medio-lateral jerkiness. Freezers also had a significantly smaller mean turn angle. In the freezers group, freezing severity was significantly associated with mean turn angle
	Camps et al., [75]	To propose a deep learning method for detection FoG episodes in PD patients	21	IMUs (Waist)	18 hours	FoG	Mean, CV	Good sensitivity and specificity of the DL method (>90%)
2017	Rodriguez-Martin et al., [79]	FoG detection with a machine learning approach based on SVM and a single tri-axial accelerometer worn at the waist	21	Rempark system (Waist)	Not detailed	FoG symptom detection	N/A	Improvement of FoG detection using SVM rather than classic technique
2016	Del Din et al., [77]	To explore the impact of environment and WB length on gait characteristics for discriminating PD and HOA group	47	Axivity AX3® (Lower back)	7 days	Step length Step velocity Swing time Step time Stance time	Mean, SD	Lower stride speed and stride length in PD compared to control group and higher stride length asymmetry. Majority of WB < 10 s (on control and PD group). Influence of WB duration on results: no difference between groups for the shortest WB, but difference for the longest WB
	Morris et al., [71]	To perform a body-worn monitor gait model from both controlled and free-living measurement	64	Axivity AX3® (Lower Back)	7 days	Swing time variability Step time variability Stance time variability Step velocity variability	Mean, SD	Gait characteristics were analyzed using principal component analysis, resulting in four factors for both groups: pace, variability, rhythm, and asymmetry. These

						Step length variability Swing time symmetry Step time asymmetry Stance time asymmetry Step length asymmetry		factors accounted for 90.% of the total variance in the control group and 93% in the PD group
2015	Mancini et al., [65]	To determine if quality of turning during daily activities is associated with falls and/or cognitive function	13	Opal® (Waist + Feet)	7 days	Turns	Mean, CV	Quality of turning was significantly compromised in recurrent fallers compared with non-fallers ($p < .05$). In contrast, activity rate and mean number of turns per hour were similar across the three groups. Also, quality of turning during a prescribed test was similar across the three groups
2014	Weiss et al., [68]	Determine whether metrics derived from a small, body-fixed sensor can capture fall risk among patients with PD	40	DynaPort® (Lower back)	3 days	Number of WB Percentage of time spent walking Total steps WB duration Number of steps Dominant peak width Harmonic ratio	Mean, CV	Freezers showed significantly higher gait variability and a wider range of dominant frequencies (vertical and side-to-side). Stride regularity in vertical, front-back, and vertical directions also differed significantly. The harmonic ratio (vertical, front-back, and side-to-side) was significantly different between the groups. Correlation with the NFOG-Q indicated that freezers had more variable, less consistent, and less smooth gait
	Tzallas et al., [66]	To assess using both short-term and long-term recordings from multiple PD patients	24	PERFORM and AGYRO system (Wrists + Ankles + Waist)	5 days	Symptoms detection : bradykinesia, tremor	Mean, SD	Acceptable patient adoption of the wearable system: valid and effective use of the device for monitoring the patient
	Weiss et al., [80]	To evaluate if long-term recordings reveal gait alterations in freezers and if these features were related to freezing severity and its impact on daily function	28	DynaPort®	3 days	time walking percentage total number of steps WB duration cadence per bout frequency derived measure : variability of the gait pattern, regularity measure : rhythmicity and consistency, and the harmonic ratio for gait smoothness	Median	Anterior-posterior width significantly correlated with clinician and motor evaluation. Anterior-posterior width was larger in the fallers compared to the non-fallers
2013	Lord et al., [72]	To quantify ambulatory activity from free-living activity	121	ActivPAL®	7 days	walking time per day time spent walking per week total step count per day distribution of WB average time spent on WB	On WB level and for each WB	Less volume activity: less time walking per day and fewer steps per day in PD group. More short WB length in PD group, less variable WB length

Table 4. Summary of 20 research articles included in the systematic review. Selection was based on bias score and information availability. (CV: Coefficient of Variation, DMOs: Digital Mobility Outcomes, FoG: Freezing of Gait, IQR: Interquartile Range, NFoG-Q: New Freezing of Gait Questionary, SD: Standard Deviation, SVM: Support Vector Machine, WBs: Walking Bouts) Bouts

4 Discussion

4.1 Overview and Findings

Research on capturing motion disorders and their progression in real-world environments, particularly in PD, is an increasingly prominent area of investigation [23]. Several well-established studies have demonstrated that individuals with PD exhibit distinct and quite specific abnormalities of gait compared to healthy controls, including reduced stride length, increased gait variability, and impaired rhythmicity [89–91]. These alterations are consistently observed both in laboratory settings and in unsupervised daily-life walking, supporting their value as robust, disease-specific digital biomarkers. Major consortia, such as Mobilise-D [92] and the Digital Medicine Society (DiMe) group [93], exemplify the growing interest in the application of digital biomarkers and wearable technologies to enhance the precision of clinical assessments. Traditional clinical tools, such as the MDS-UPDRS-III, are widely used but come with significant limitations. These include inter- and intra-rater variability, the provision of only a "snapshot" of the patient's condition at a single time point, and limited sensitivity in detecting subtle changes in the progression of the disease [5]. While these clinical scales offer a broad understanding of the impact of PD on motor function, they continue to be considered the gold standard for assessing the status of the patient and their therapeutic response [4]. Additionally, patient-reported outcomes (PROs) are often used to assess specific motor symptoms of PD, such as Freezing of Gait (FoG) and difficulty in turning, both of which are hallmark features of the condition. In this context, wearable sensors offer a complementary perspective by enabling continuous, objective monitoring of motor activity in the patient's natural environment. Rather than replacing traditional assessments, real-world gait assessment derived from wearables can enrich clinical evaluations by capturing fluctuations across daily life and providing ecologically valid insights into motor behavior. The application of wearable devices in real-world studies introduces also a number of methodological challenges, ranging from the design of the protocol and the collection of the data to the analysis of the signals and its clinical relevance. This review aims to provide a comprehensive synthesis of the recurring themes in protocol design, signal processing workflows, and the interpretation of DMOs from wearables. Most of the studies reviewed were observational, with objectives ranging from validating a wearable system to using DMOs as primary outcomes in interventional trials. The diversity of these objectives reflects the current exploratory phase of digital healthcare in PD. Yet, substantial variation exists in the technical characteristics of the devices and protocols, especially between studies conducted in controlled laboratory settings and those capturing data in real-world environments. This lack of consensus complicates the generalization of findings across studies and patient populations.

As summarized in Table 3, several DMOs differentiate Parkinson's patients from healthy controls and may reflect disease severity. However, the studies are highly heterogeneous in terms of design, sensor types, and outcome definitions, which prevents formal meta-analysis. This qualitative summary highlights promising DMOs while underscoring the need for standardized protocols in future research.

4.2 Devices and Protocols

This review highlights the diversity of wearable devices used in studies of PD. A key recommendation for future research is the selection of devices that include both a 3D accelerometer and a gyroscope. This combination of sensors is essential for accurately detecting gait events, such as heel strikes and toe-offs, which are critical for understanding locomotor impairments in PD. Beyond the technical specifications, the ability to access raw data from the device should be a primary consideration, as this would allow a more transparent and flexible analysis. Furthermore, the technical specifications must align with the practical demands of real-world recording, including battery life, the weight of the device, and the number of sensors used.

Moreau et al. (2023) [94] provides an overview of the most commonly used sensors, evaluating their respective strengths and weaknesses. While they show that most sensors are typically placed on the lower back, it is essential to consider the sensor's specifications, the gait detection algorithm, and the specific needs of the study. The gait events sought in the signal will also affect the sensor's localization (turn detection, sit-to-stand transitions, which may require localization on the trunk, upper limb, or head).

Another important but often underreported source of methodological variability lies in the calibration of the IMU sensors. The calibration procedures and the quality of the recorded time-series are rarely

detailed in published studies, despite their critical influence on the integrity of the signal and and the reliability of the measurement. Sensor bias (including misalignment, offset drift, and hardware inconsistencies) can directly affect the accuracy of the gait parameter estimation. While only a few studies explicitly addressed these issues, those that did tended to demonstrate greater methodological transparency and reliability. In the context of real-world gait monitoring, the potential impact of uncorrected sensor bias must be acknowledged, as it may compromise the interpretability of subtle temporal or spatial gait features. Future studies should aim to document the calibration protocols and evaluation of the quality of the time-series more systematically, or at least report how sources of potential bias were handled or mitigated.

Another crucial consideration is the duration of the recordings, which should be carefully tailored to the specific research question. For instance, if the goal is to study short-term events such as freezing of gait, a short recording period may suffice, whereas longitudinal studies may require devices to be worn over extended periods. Debelle et al. (2023) [95] demonstrated good patient acceptability of wearable devices when used for a one-week recording period, supplemented by a daily journal for tracking adherence. However, the usability of these devices must not be overlooked. As Keogh et al. [96] emphasize, usability evaluations should be conducted in close collaboration with the patients to ensure that the devices are not only functional but also well-tolerated and effectively used.

4.3 Sampling Frequency and Signal Analysis

In motion analysis research, a key parameter is the sampling frequency of the device. Bouten et al. (1997) [97] established that a sampling frequency of approximately 120 Hz is ideal for capturing the fine details of human locomotion, such as heel strikes. In the present review, 74% (40/54) of the studies adhered to this recommendation, using frequencies between 100 and 150 Hz. However, a number of studies used significantly lower frequencies, with some as low as 10 Hz [71]. This is a notable concern, as low-frequency sampling may be inadequate for capturing detailed movement events. When studies opt for such low frequencies, it is crucial that they clarify which specific types of movement they are targeting, as certain gait events may be missed or misrepresented. In terms of signal analysis, the most common method for detecting gait events is the identification of peaks in the signal that correspond to key phases of the gait cycle, such as initial contact and terminal stance. This approach has been the gold standard for over a decade and many algorithms developed during this period are still in use. However, they are difficult to calibrate and have intra-individual variation. More advanced techniques are emerging, including machine learning-based pattern recognition algorithms that have the potential to identify gait patterns even in cases of significant gait impairment, such as freezing episodes. These advanced techniques are able to capture gait events without any threshold. Although promising, these newer approaches are still at an exploratory stage and require further validation before they can be widely adopted.

4.4 Transparency and Standardization

A recurring issue in studies using wearables is the transparency of the data processing workflows. Commercially available wearables that allow access to raw data tend to offer greater transparency, as they enable researchers to apply their own methods of analysis. In contrast, studies that rely on data from smartphones or smartwatches often do not specify how the DMOs are computed, leading to potential inconsistencies in the findings. Across the studies reviewed, spatiotemporal DMOs, especially walking speed, were the most commonly reported outcomes. This aligns with the broader consensus that walking speed is a reliable proxy for functional health and mobility status. Despite these promising findings, two significant limitations arise when conducting studies in uncontrolled, real-world environments. First, there is often no verification mechanism to ensure that the patients are using the devices correctly. This can lead to unreliable or incomplete data. Second, the diversity in signal processing methods introduces a variability in the reported DMOs. For instance, differences in how the signals are segmented into episodes of walking, or how noise is filtered, can dramatically affect the results. This underscores the urgent need for greater standardization in both data collection and signal analysis to ensure the clinical relevance of the findings.

In this context, the choice of analytical models and the potential role of more advanced machine learning approaches deserve specific consideration. This review highlights a predominant use of structured signal-processing pipelines relying on activity detection, gait event detection, walking bout segmentation,

and the computation of explicit spatiotemporal DMOs. Rule-based methods and conventional machine learning approaches remain widely used, as they provide robust and clinically interpretable outcomes in real-world settings. More advanced analytical models, including deep learning architectures such as convolutional or recurrent neural networks applied to raw inertial signals, offer promising opportunities to capture complex and non-linear gait alterations, particularly for symptoms such as freezing of gait or highly variable walking patterns. However, their adoption remains limited due to heterogeneous protocols, modest sample sizes, limited access to annotated datasets, and challenges related to interpretability, reproducibility, and clinical validation. Future research should explore hybrid approaches combining biomechanically meaningful features with advanced machine learning models, alongside standardized validation frameworks, to ensure that methodological innovation translates into clinically meaningful digital mobility outcomes. This limitation of conventional statistical approaches is not specific to wearable-derived data and has also been reported in a posturographic study, where a machine learning–based multivariate test successfully distinguished fallers from non-fallers in Parkinsonian syndromes, while standard univariate analyses did not [98].

4.5 Recommendations for Future Research

Given that wearable technology in PD research has been in an exploratory phase for over a decade, there is now a pressing need for standardization. Precise technical specifications must be established, along with quality standards that ensure the integrity of the data from collection through to clinical interpretation. Initiatives such as DiMe [93] are leading efforts to develop standardized validation frameworks, including the 3V framework, which outlines steps for sensor verification, analytical validation in controlled environments, and clinical validation to assess the relevance of DMOs in real-world settings. Similarly, the Mobilise-D consortium and Kluge et al. [88] are working to establish a common terminology and set of standards for DMOs. A key recommendation of this review is that future studies follow the DiMe 3V validation framework. This process begins with sensor verification, ensuring that the devices meet specific technical requirements. The next step is analytical validation, where the device is tested in a controlled environment against a reference system to ensure the accuracy of its DMOs. Finally, clinical validation assesses the meaningfulness of its DMOs in real-world contexts, ensuring that they are relevant to clinical outcomes. In addition, the design of the protocol must be tailored to the specific research question. For example, if the aim is to identify DMOs that are correlated with traditional clinical scales, this should be clearly stated and the protocol should be designed to facilitate such a determination. In studies aimed at identifying early biomarkers of a disease or tracking the progression of PD, longer follow-up periods and more complex monitoring tools (e.g., home visits, diaries, or smartphone applications) may be needed to ensure data quality. Furthermore, it is strongly recommended that research teams adhere to well-established gait event detection algorithms [76, 99]. Standardising these methods will not only facilitate comparison between studies, but will also ensure that new, innovative algorithms are based on proven techniques. For more complex techniques, such as those based on deep learning, it is essential that these methods are made accessible and interpretable to the wider scientific community to ensure their widespread adoption. Another important transparency relates to the definition of the WB. The number of steps, duration, distance between two consecutive WBs, and filtering of information at the WB level are necessary to harmonise the calculation and interpretation of DMOs.

Finally, successful real-world studies depend on close collaboration between computer scientists, clinicians and patients. Both the patients and the clinicians need adequate training to use the equipment effectively, and ongoing interdisciplinary collaboration is required to ensure that the methods of the analysis are aligned with the underlying clinical and scientific questions. Such a collaborative approach is essential for the successful implementation of wearable devices in both clinical practice and research. In conclusion, the fragmentation of methods currently observed in real-world studies of PD is a significant barrier to progress and makes meta-analysis difficult in the review. By standardizing wearable devices, sensor placement, and event detection methods, the field can move toward more reliable and clinically meaningful DMOs. This, in turn, will support the development of new biomarkers and endpoints for clinical trials and broader clinical research.

5 Conclusion

In conclusion, this review has provided a comprehensive overview of current studies on motor function in Parkinson's disease (PD) in real-world settings using wearable devices. Wearable sensors can be used in patients with PD and effectively provide clinically relevant information. Spatiotemporal Digital Mobility Outcomes (DMOs) are the most commonly measured characteristics and show great promise for routine clinical practice and research, as demonstrated by stride speed measurements. However, the lack of consensus on the methods of assessment, patient compliance with monitoring, quality of recorded data, inertial signal analysis, and small sample sizes represent significant barriers. Addressing these issues is essential to enable meta-analyses and facilitate wider adoption in both clinical practice and research.

6 Limitations

This work adheres to the PRISMA method and provides an update in the rapidly evolving field of digital healthcare for patients with PD. It includes a comprehensive analysis grid covering the design of the protocol, the analysis of the inertial data, and clinical interpretation and relevance. Such a multidisciplinary effort is essential, given the integration of applied engineering sciences with clinical practice.

However, it includes searches in only four databases and excludes gray literature; supplementing this research with additional complementary databases would be valuable. The lack of quality of some studies and the heterogeneity of the results prevented the realization of a meta-analysis. Two major obstacles arose: first, the objectives and methods of the studies assessing feasibility diverges from those focused on the clinical relevance of DMOs, which is incompatible with a meta-analysis. Second, the diversity of methods used to calculate the DMOs and analyze the resulting data requires specific discernment, complicating the execution of a meta-analysis.

In the future, it will be important to determine whether a sufficient number of studies with adequate standardization are available to conduct a meta-analysis on relevant DMOs for assessing motor symptoms in PD.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

All authors have read and agreed to the published version of the manuscript.

Availability of data and materials

Not applicable.

Competing interests

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Authors' contributions

Conceptualization: M.M., N.dE., L.O. and D.R.; Formal analysis: M.M., N.dE., C.V., L.O. and D.R.; Methodology: M.M., N.dE., C.V., L.O. and D.R.; Supervision: N.dE., L.O. and D.R.; Writing original draft: M.M., N.dE., C.V., L.O. and D.R.; Writing review and editing: M.M., N.dE., C.V., L.O. and D.R.

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Appendix A Research equation used in Medline, COCHRANE and Embase

Database	Date of research	Search equation
Medline wia PubMed	15/09/2023	(parkinson) AND ((gait) OR (walk) OR (steps)) AND ((sensors) OR (IMU) OR (accelerometer) OR (gyroscope) OR (wearable) OR (motion analysis)) AND ((real world) OR (FLE) OR (remote monitoring) OR (daily living) OR (real condition) OR continuous home monitoring))
COCHRANE	18/09/2023	Parkinson + gait + wearable + real world [2013-2023]
Embase	02/11/2023	(parkinson AND ('disease'/exp OR disease) AND ('gait'/exp OR gait) AND ('study'/exp OR study) AND wearable OR IMU) AND ('real'/exp OR real) AND ('world'/exp OR world) AND ('monitoring'/exp OR monitoring) AND [2013-2023]/py

Appendix B Risk of bias grid evaluation

Additional file 2: 20-item quality checklist

Reporting

1. Is the hypothesis/aim/objective of the study clearly described? (1 point)

2. Are the main outcomes to be measured clearly described in the Introduction or Methods section? (1 point)

If the main outcomes are first mentioned in the Results, the score should be 0.

3. Is the protocol clearly described? (2 points)

The description should include the following five elements: location of the device on the body, number of devices used, recording period duration (months, days, hours), compliance metrics (cloud, specific application, notebook), environment (real-world only, controlled environment and real world). Assign 0 points if two or more elements are missing, 1 point if one element is missing, 2 points if the eight elements are specified.

4. Are inertial data analysis methods clearly described or referred to? (1 point)

The description should include the following five elements : nature of the raw signal (accelerometer, angular velocity, both), if so, walking bout detection definition, stride detection, computed digital mobility outcomes, aggregation.
Award 0 point if two or more elements are not well described, 1/2 point if one element is not well described, 1 point if all elements are well described.

5. Are the number of hours recorded and strides included in the analysis clearly specified? (1 point)

6. Are the characteristics of the patients included in the study clearly described? (1 point)

In cohort studies and trials, the inclusion and/or exclusion criteria should be given. In case–control studies, a case-definition and the source for controls should be given.

7. Are the distributions of principal confounders in each group of subjects to be compared clearly described? (2 points)

A list should be given.

8. Are the main findings of the study clearly described? (1 point)

When they exist, quantitative findings should be reported in the Results section and discussed in the Discussion section for the main findings.

9. Does the study provide estimates of the random variability in the data for the main outcomes? (1 point)

For non-normally distributed data, the interquartile range should be reported. For normally distributed data, the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the item should be scored 1.

10. Have actual probability values been reported (eg, 0.035 rather than <0.05) for the main outcomes (when significant) except where the probability value is less than 0.001%? (1 point)

When no result is significant, the item is not quoted.

External validity

11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited? (1 point)

The study must identify the source population for patients and describe how the patients were selected. Patients will be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible when a list of all members of the relevant population exists. When a study does not report the proportion of the source populations from which the patients are derived, the score should be 0 (unable to determine).

12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited? (2 points)

The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

13. Was there validation of the sensor used? (1 point)

If the sensor is self-made and no analysis of reliability was evident in the article or a previous article, the score should be 0.

Internal validity - Bias

14. If any of the results of the study were based on "data dredging", was this made clear? (1 point)

Any analyses that were not planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then score 1.

15. Were the statistical tests used to assess the main outcomes appropriate? (1 point)

If no test for normality or no post-hoc corrections was performed when needed, only 1/2 point should be given. If both criteria fail, score should be 0.

16. Were the main outcome measures used accurate (valid and reliable)? (1 point)

For studies for which the outcome measures are clearly described, the score should be 1. For studies that refer to other work or demonstrate that the outcome measures are accurate, the score should be 1.

Internal validity - Confounding (Selection Bias)

17. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? (1 point)

Patients for all comparison groups should be selected from the same hospital(s) or institution(s). Patients and controls should not have significantly different ages. No point should be given when no information can be found regarding the source of patients included.

18. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? (1 point)

19. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? (1 point)

This question should be scored 0 for trials if the main conclusions of the study were 1) based on analyses of treatment rather than intention to treat; 2) the distribution of known confounders in the different treatment groups was not described; or 3) the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. For non-randomised studies, if the effect of the main confounders was not

investigated or confounding was demonstrated but no adjustment was made in the final analyses, the question should be scored 0.

Power

20. Did the study have sufficient power to detect a clinically important effect if the probability for a difference due to chance is less than 5%? (5 points)

	Size of smallest group	Power estimate	Score
A	<n1	70%	0
B	n1-n2	80%	1
C	n3-n4	85%	2
D	n5-n6	90%	3
E	n7-n8	95%	4
F	n+	99%	5

Appendix C Total risk of bias score for each of the 63 included studies

C.1 Individual score

Title	Authors	References	Total RoB score
Translating digital healthcare to enhance cli	Emma Packer ,1 Héloïs	[26]	14
Can Digital Mobility Assessment Enhance th	Kirk C, Zia Ur Rehman	[27]	23
Wearable multisource quantitative gait ana	Xie J, Zhao H, Cao J, Q	[28]	16
Assessing real-world gait with digital techn	Micó-Amigo ME, Bonc	[29]	22
A multi-sensor wearable system for the ass	Francesca Salis1,2*, St	[30]	19
Clinical Evaluation in Parkinson's Disease: Is	Kanellos FS, Tsamis KI,	[31]	13
Feasibility and patient acceptability of a cor	Liikkanen S, Sinkkoner	[32]	18
Deploying Digital Health Technologies for R	Waddell KJ, Patel MS,	[33]	21
Multidisciplinary Intensive Rehabilitation Pr	Cohen M, Herman T, G	[81]	17
Design and validation of a multi-task, multi	Kirsty Scott 1 2, Tecia I	[34]	22
TURN-IT: a novel turning intervention progr	King LA, Carlson-Kuhta	[82]	16
Fall Risk Prediction in Parkinson's Disease U	Ullrich M, Roth N, Kud	[35]	NA
Connecting real-world digital mobility asses	Mikolaizak AS, Roches	[36]	16
Daily-Living Freezing of Gait as Quantified U	Diana Denk 1, Talia He	[83]	NA
Reliability and validity of the Roche PD Mob	Lipsmeier F, Taylor KI,	[58]	20
Real-World Stair Ambulation Characteristics	Nils Roth , Member, IE	[38]	20
Investigating the Impact of Environment an	Rehman RZU, Guan Y,	[39]	19
Do We Walk Differently at Home? A Contex	Roth N, Wieland GP, K	[40]	16
Technical validation of real-world monitorir	Mazzà C, Alcock L, Am	[41]	15
A real-world study of wearable sensors in P	Adams JL, Dinesh K, Sr	[42]	21
Protocol for the DeFOG trial: A randomized	Demi Zoetewei a,*, Ta	[84]	15
Detection of Unsupervised Standardized Ga	Ullrich M, Mucke A, Ku	[43]	11
Remote smartphone monitoring of Parkinso	Larsson Omberg 1,10 ,	[44]	20
Feasibility of a Mobile-Based System for Un	Raquel Bouça-Machad	[45]	15
Comparison of Laboratory and Daily-Life Ga	Marta Francisca Corrà	[46]	19

Machine learning-based motor assessment	Abujrida H, Agu E, Pah	[47]	23
Measuring freezing of gait during daily-life:	Martina Mancini1* , V	[48]	20
Laboratory versus daily life gait characterist	Vrutangkumar V. Shah	[49]	20
Probabilistic Modelling of Gait for Robust P	Yordan P. Raykov , Luc	[50]	14
Real-Life Gait Performance as a Digital Biom	Luc JW Evers1,2, BSc; '	[15]	18
Digital Biomarkers of Mobility in Parkinson'	Vrutangkumar V. Shah	[51]	18
Entropy of Real-World Gait in Parkinson's D	Lucy Coates 1, Jian Shi	[52]	20
Building a Machine-Learning Framework to	Chen OY, Lipsmeier F, I	[53]	20
Quantity and quality of gait and turning in p	Shah VV, McNames J,	[54]	21
Identification of Motor Symptoms Related t	Jauhiainen M, Puustin	[55]	13
Associations between daily-living physical a	Galperin I, Hillel I, Del	[56]	18
Patient-reported and performance-based m	Leavy B, Löfgren N, Nil	[57]	18
Evaluation of smartphone-based testing to	Lipsmeier F, Taylor KI,	[37]	19
A Kinematic Sensor and Algorithm to Detec	Rodríguez-Molinero A,	[59]	17
Turn Around Freezing: Community-Living Tu	Mancini M, Weiss A, H	[60]	22
Towards holistic free-living assessment in Pl	Godfrey A, Bourke A, I	[61]	9,5
Factors Associated With Ambulatory Activit	Christiansen C, Moore	[62]	19
Objective characterization of daily living tra	Bernad-Elazari H, Herr	[63]	19
Randomized Controlled Trial of a Home-Bas	Jaywant A, Ellis TD, Ro	[85]	16
Continuous monitoring of turning in Parkins	Mancini M, El-Gohary	[64]	16
PERFORM: a system for monitoring, assessr	Tzallas AT, Tsipouras M	[65]	13
Comparison of two accelerometer filter set	Wallén MB, Nero H, Fr	[66]	20
New evidence for gait abnormalities among	Aner Weiss • Talia Her	[67]	19
Automated detection of missteps during co	Iluz T, Gazit E, Herman	[68]	19
Feasibility study of a wearable system base	Cancela J, Pastorino M	[69]	17
A model of free-living gait: A factor analysis	Rosie Morris, Aodhán	[70]	17

Ambulatory activity in incident Parkinson's:	Sue Lord • Alan Godfr	[71]	23
Analysis of Free-Living Gait in Older Adults	Silvia DelDin,PhD,1Bro	[72]	21
Assessing Motor Fluctuations in Parkinson's	Carlos Pérez-López 1,*	[73]	12
Deep learning for freezing of gait detection	Juli`a Campsa, Albert S	[74]	12
Determining the optimal features in freezin	Albert Samàa#, Daniel	[75]	6
Falls Risk in Relation to Activity Exposure in	Silvia Del Din, PhD,1, E	[86]	21
Free-living gait characteristics in ageing and	Silvia Del Din*, Alan G	[76]	21
Gait speed in clinical and daily living assess	Arash Atrsaei 1,2 ✉, M	[77]	19
Home detection of freezing of gait using su	Daniel Rodrı´guez-Mar	[78]	14
Impact of motor fluctuations on real-life ga	Ana Lígia Silva de Lima	[87]	22
Objective assessment of fall risk in Parkinso	Aner Weiss1, Talia Her	[79]	23
The Impact Of Freezing Of Gait On Balance	Martina Mancini [Mar	[80]	14

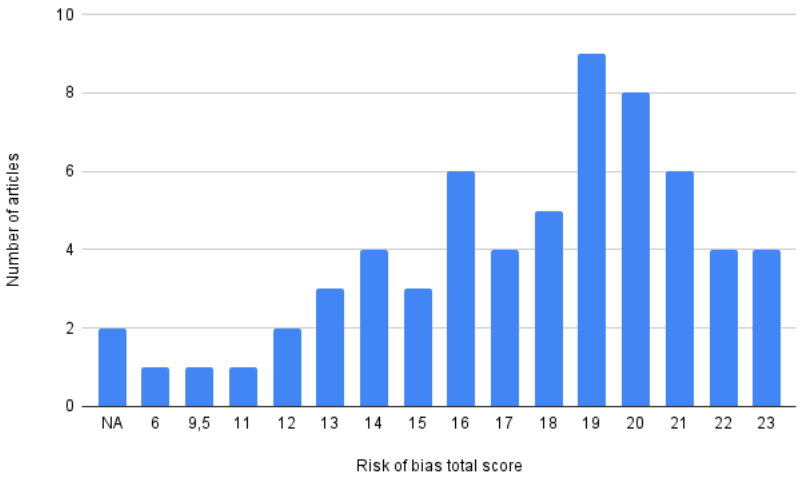

Fig. C1 Repartition of the overall risk of bias score

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