**REVIEW ARTICLE** 



### Vibrotactile biofeedback devices in Parkinson's disease: a *narrative* review

Helena R. Gonçalves<sup>1</sup> · Ana Margarida Rodrigues<sup>2</sup> · Cristina P. Santos<sup>1</sup>

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#### Abstract

Parkinson's disease (PD) is often associated with a vast list of gait-associated disabilities, for which there is still a limited pharmacological/surgical treatment efficacy. Therefore, alternative approaches have emerged as vibrotactile biofeedback systems (VBS). This review aims to focus on the technologies supporting VBS and identify their effects on improving gait-associated disabilities by verifying how VBS were applied and validated with end-users. It is expected to furnish guidance to researchers looking to enhance the effectiveness of future vibrotactile cueing systems. The use of vibrotactile cues has proved to be relevant and attractive, as positive results have been obtained in patients' gait performance, suitability in any environment, and easy adherence. There seems to be a preference in developing VBS to mitigate freezing of gait, to improve balance, to overcome the risk of fall, and a prevalent use to apply miniaturized wearable actuators and sensors. Most studies implemented a biofeedback loop able to provide rescue strategies during or after the detection of a gait-associated disability. However, there is a need of more clinical evidence and inclusion of experimental sessions to evaluate if the biofeedback was effectively integrated into the patients' motor system.

Keywords Parkinson's disease · Gait-associated disabilities · Biofeedback systems · Vibrotactile cueing

#### 1 Introduction

Parkinson's disease (PD) is often associated with a vast list of gait-associated disturbances, as episodes of akinesia (difficulty in starting the movement), bradykinesia (slow movement), rigidity, postural instabilities, tremors (rhythmic movements in a resting position), and events of freezing of gait (FOG) [1–3]. These disabilities considerably increase the risk of fall, limit the quality of life and autonomy of the patients, who become dependent on third parts for the most trivial and daily activities.

Biofeedback systems are a promising solution for mitigate *parkinsonian* gait-associated disabilities besides to be easily accepted by patients [4]. These systems make use of wearable

Helena R. Gonçalves id7609@alunos.uminho.pt technology that enable sensory acquisition and trigger a cueinformation (bio-feedback) [4, 5]. They can detect an increase in cadence or a change of the lower leg oscillations, and through the detection of such motor behaviors deliver proprioceptive cues [6-8]. Sensory cues could lead to a change in postural control, stepping pattern, unfreezing gait-blocks, prevent falls, and, consequently, to promote less gait variability and a more goal-oriented gait. Further, wearable systems allow their integration into patients' daily tasks, ensuring greater freedom of movement and comfort for patients [9]. Indeed, the use of external cues is a well-established technique that has been shown to improve gait in parkinsonian patients, including increasing walking speed, step length, cadence, and reducing the number of FOG episodes [7]. These cues include the use of external stimuli (vibrotactile, visual, or auditory) which provide temporal or spatial information to facilitate motion initiation and continuation. External cues are not simple stimuli, but rather give information on how an action should be carried out [5, 7, 10, 11].

Cassimatis et al. [12] presented a systematic review about the effects of external sensory cues on daily living activities of patients with PD, concluding that all studies yielded positive

<sup>&</sup>lt;sup>1</sup> Center for MicroElectroMechanical Systems, University of Minho, Guimarães, Portugal

<sup>&</sup>lt;sup>2</sup> Neurology Service, Hospital of Braga, Braga, Portugal

findings in favor of external sensory cues use. Although a number of biofeedback systems used on PD reviews have been presented in the literature to date, such reviews tend to focus mainly on devices to avoid freezing episodes, as cited in [5, 13, 14]. To the best of our knowledge, there is no existing research which includes biofeedback systems developed for different applications in PD motor symptomatology beyond FOG, such as to improve balance or avoid the occurrence of falls [12–17]. Particularly, the use of vibrotactile cues has proved to be relevant and attractive, as positive results have been obtained in patients' gait performance, they showed suitability in any environment and easy acceptance. Also, vibrotactile cues do not require sensory skills that can be affected with age, such as vision or hearing. Thus, future research in vibrotactile biofeedback systems for PD rehabilitation and assistance should be driven by the remarkable achievements and current limitations.

In light of the need to better understand the state of the art along the last 10 years, this comprehensive review surveys vibrotactile biofeedback systems (VBS) used in PD to mitigate gait-related disabilities. A description of the technology that supports these systems is provided, including the identification of electronic components and their operating parameters. A new organization of the applied mechanisms of biofeedback associated with the VBS's objectives is proposed. Additionally, the validation methodologies are analyzed (study population, protocols, criteria study metrics, and VBS effects) and assessed using a validated tool. VBS research are thoroughly compared, in terms of technological and validation issues, and their impact on the level of usability and acceptability (e.g., what is the patient feedback about the device ergonomics or a type of treatment). Paper findings culminate with a review of current VBS's challenges and key solutions based on user-centered design. This manuscript aims to serve as a reference point for future research in VBS.

The following questions were investigated and answered: (i) Which are the technologies integrated in VBS and where are they placed? (ii) How have the biofeedback loops been applied in VBS to mitigate parkinsonian gait-associated disabilities? and (iii) How have VBS been clinically validated? The first question offers a more technological revision than review [12], with a focus on the use of vibrotactile cues. The second research question allows to complement the reviews [5, 13, 14], which focused on biofeedback systems to mitigate FOG. The last question offers a review of experimental methodologies to validate the VBS, which for the best knowledge of the authors have not been identified. The holistic view of this review enables to identify the areas of clinical practice and the methodology employed for its validation. The paper findings are intended to be instructive for further researchers looking to enhance the effectiveness of future VBS.

#### 2 Methods

#### 2.1 Data sources, search strategy, and study selection

An electronic systematically search was carried out on databases as Google Scholar, PubMed, and Web of Science. The survey was conducted according to the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), as depicted on Fig. 1 [18]. For that purpose, keywords matching headings were used: ["Parkinson's Disease AND Biofeedback"]; ["Sensory Cues AND Vibrotactile Biofeedback"]; ["Vibrotactile AND Parkinson's Disease"]; ["Sensory Cues AND Parkinson's Disease"]; ["Vibratory AND Parkinson's Disease"]; and ["Rehabilitation AND Parkinson's Disease"].

Studies were included if they fulfilled the following inclusion criteria: (i) studies of idiopathic PD; (ii) vibrotactile cueing systems were used as part of rehabilitation or assistance strategies; (iii) applicability to mitigate/improve parkinsonian gait-associated disabilities, especially, FOG, balance, and falls; (iv) the interventions were implemented with individuals with PD (both sexes, all ages, and any disease duration/scale); (v) wearable technology was integrated; and (vi) results were published in the English language and within the past 10 years. The exclusion criteria were (i) studies not validated with patients with PD; (ii) validation of exclusively open-loop cueing strategies; and (iii) studies that assessed interventions to improve other non-motor symptoms in PD, as mood disorders or cognitive changes. The articles' reference lists were searched for additional reports.

#### 2.2 Assessment of study quality

Critical Appraisal Skill Programme (CASP) includes a set of checklists which enable the researchers to assess the trustworthiness, relevance, and results of published papers. Given the non-homogeneity in the design of the included studies, it used a CASP-based checklist to study the case control studies: CASP Case Control Study Checklist. Thus, firstly, it was considered if the researchers applied case control studies. This approach enables to answer (i) if the study is valid, (ii) what are the study results, and (iii) if the results are useful. Two authors (Helena R. Gonçalves and Cristina P. Santos) rated the items of the CASP checklist and then compared the differences in rating to reach an agreement.

#### **3 Results**

#### 3.1 General results

A total of 147 articles were identified: Google Scholar (n = 49), PubMed (n = 45), and Web of Science (n = 53) databases.

Fig. 1 Flowchart for the search strategy based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)



Duplicates were removed (n = 96). Articles were excluded if they have the following keywords on titles (n = 7) and abstracts (n = 6): deep brain stimulation, surgical intervention, drug therapy, physiotherapy, and treadmill training. In case the abstract of an article did not provide enough information to determine its eligibility, the full article was reviewed. Next, the full-text papers were reviewed to meet the inclusion criteria and 11 articles met the eligibility criteria and were included in this review. These reports were grouped and discussed according to their application goal, i.e., VBS used (1) to mitigate FOG, (2) to improve balance, and (3) to decrease the risk of falls. As a result, five VBS were identified to overcome FOG, three VBS to improve balance, and three VBS to overcome the risk of fall. Firstly, we discriminated the technological components, their settings of operation, and highlighted the devices' wearability issues. Then, we analyzed

the adopted biofeedback strategies, the validation methodology highlights, and their quality assessment.

#### 3.2 Technology supporting VBS

Table 1 presents the VBS developed over the past 10 years to mitigate gait-associated disabilities in PD, highlighting their technological components. VBS comprises three main systems: (1) actuation system, (2) sensory system, and (3) control/processing unit. The actuation system is responsible for providing vibrotactile cueing, whereas the sensory system acquires a physiological measurement. The control/processing unit runs an algorithm able to receive the sensory-acquired data, process, control, and decide when the actuation system should be activated.

VBS			Actu	ation sys	stem	Sensory system			l	Drocosing	Single
Goal	Ref.	D	Ν	L	f [Hz]	D	N	L	fs [Hz]	unit	device
	[19]	ERM	2	Ankle	-	IMU	2	Ankle	50	FPGA	$\checkmark$
	[20]	LRA	1	Wrist	200-300	IMU	1 2	Trunk Shins	128	ATmega328	×
FOG	[21]	LRA	1	Wrist	200-300	IMU	1 2	Trunk Shins	128	ATmega328	×
	[22]	ERM	2	Ankle	-	IMU	2	Ankle	8		$\checkmark$
	[23]	ERM	2	Insole	275	IMU FSR	1 2	Ankle Insole	44		$\checkmark$
	[24]	LRA	4	Waist	250	IMU	1	L5/S1	100	-	$\checkmark$
Balance	[25]	ERM	8	Waist	-	Force plate	1	nW	600		×
	[26]	ERM	8	Head	250	Gyr	2	L1/L3	-	-	×
Falls	[27]	ERM	1	Insole	-	Acc FSR	1 4	Ankle Insole	100		$\checkmark$
	[28]	ERM	2	Head	200	Gyr	2	Knee	1000	-	×
	[29]	ERM	4	Hip	250	Gyr	1	Hip	80	ATMega168	$\checkmark$

 Table 1
 VBS developed over the past 10 years to mitigate gait-associated disabilities in PD regarding their technological components

[Ref.]: study reference; D: device; N: number; L: location; f: vibratory frequency; fs: sampling frequency; Appr.: algorithmic approach; Proc.: processing unit used to run the algorithm; Strat.: Biofeedback strategy; IMU: Inertial Measurement Unit; FSR: Force Sensor Resistive; Acc: accelerometer; Gyr: gyroscope; FPGA: Field Programmable Gate Array; nW: Not wearable;  $\square$ : smartphone;  $\blacksquare$ : computer;  $\checkmark$ : yes; and  $\varkappa$ : no.

Concerning the actuation system, the type and number of devices, their location, and vibratory frequency were identified. All systems used vibratory motors based on rotary and linear electromagnetic actuators. The eccentric rotating mass (ERM) motors identified in [19, 22-27, 29] correspond to a rotary electromagnetic actuator and the linear resonance actuator (LRA) motors identified in [20, 21, 24] concern to linear electromagnetic actuators. The number of actuators used was usually one [20, 21, 27] and two [19, 22, 23, 28], but when the actuators were placed around the torso, hip, or head, the used number increased to four [24, 29] and eight [25, 26]. The used vibratory frequency varied within the 80-300 Hz range of the skin mechanoreceptor perception [30], which are responsible for decoding the vibrotactile information: [20, 21] used a vibratory frequency range of 200-300 Hz; [28] used a range of 200 Hz; [24, 26, 28] used 250 Hz; and [23] used 275 Hz.

Inertial measurement units (IMU) were the sensors usually integrated into the VBS [19–24]. They were placed in the ankle [19, 22, 23, 27], lower trunk [24, 26], knees [28], shins [20, 21], and hip [29]. Sensors based on plantar force measurements were also employed in [23, 27], placing force sensor resistive (FSR) on insoles. Although this review selected studies which used wearable technology, we exceptionally included [25], since their sensory system, while not wearable (a force plate), measured a user sensory response (trunk angular velocity) to provide biofeedback. All these systems provided information of the patients' gait or balance. The frequency of sampling varied widely between systems: 8–128 Hz on systems focusing freezing of gait [19–23]; 100–600 Hz on systems aiming to improve balance [24–26]; and 100–1000 Hz when addressing the risk of falls [27–29]. When applicability concerns motor balance or fall prevention, the acquisition frequency range (80–1000 Hz) is higher than VBS applied to mitigate FOG.

The processing unit usually used was smartphones [22, 27], computers [23, 25], and Arduino boards [20, 21, 29]. Recently, [19] designed a FPGA oriented specifically to run their algorithm of FOG detection and vibrotactile actuation.

Regarding wearability issues, in [19, 22, 27, 29], all systems' components were integrated on a single-one device, making them compact systems. Finally, for some of the newer systems that addressed FOG, there is a 500 and 800 mA battery current consumption and gram-weighted systems of 32 g [19] and 170 g [22].

#### 3.3 Biofeedback strategies

We propose to organize the VBS objectives as shown in Fig. 2 [14]: (1) to preserve optimal patient's gait/balance control, thereby preventing FOG, postural instabilities, and falls [20, 21, 24–29]; and (2) to implement rescue strategies once an episode of gait-associated disorder has occurred [19, 22, 23]. Also, Fig. 2 depicts the roles for biofeedback mechanisms according to VBS objectives: (a) a stabilizing role by



providing biofeedback to preserve or improve gait parameters or balance [24–26, 28, 29]; (b) an augmentation role by delivering sensory cueing, i.e., provide biofeedback as a technique of re-integration and coupling postural control with stepping [20, 21, 27]; and (c) a replacement role, known as sensory substitution [19, 22, 23], by providing sensory cueing in order to facilitate motor response generation. Table 2 presents the identified studies regarding their aims, the underlying role of biofeedback mechanism, the implemented algorithm, and the vibrotactile cue-trigger signals.

#### 3.3.1 Biofeedback strategies to mitigate FOG

Mikos et al. [19] provided vibrotactile information on the ankle when a FOG event was detected. FOG event detection was based on the processing of the acceleration and angular velocity signals of the patients' ankle, by a machine learning tool (neural network). Also, Punin et al. [22] provided vibrotactile biofeedback when a FOG episode was detected based on IMU data, located on shins, by a discrete wavelet transform. Similarly, in [23], FOG were automatically detected through fast Fourier transform analysis based on data from a IMU and FSRs, and once a freezing event was detected, a vibratory stimulus was produced on the sole.

Mancini et al. [20] and Harrington et al. [21] explored the use of biofeedback as an augmentation role for ameliorating FOG and applied biofeedback during the stance gait phase. To investigate the patients' difficulties in turning as a trigger factor for freezing events, Mancini et al. [20] studied the effectiveness of open-/closed-loop cueing in improving turning characteristics. Vibrotactile cues were delivered through a wearable system, the VibroGait. Previously, this system was validated by Harrington et al. [21] in order to test the benefits of applying biofeedback to alleviate freezing, also focusing on turnings.

#### 3.3.2 Biofeedback strategies to improve balance

Lee et al. [24] explored the effects of two coding schemes (binary vs continuous) for vibrotactile biofeedback during dynamic weight-shifting exercises. The biofeedback was

Table 2VBS developed over the past 10 years to mitigate gait-associated disabilities in PD regarding the system objective, the mechanism ofbiofeedback, algorithm implemented, and the vibrotactile cue-trigger signals

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[Ref.]: study reference; (1): Preserve optimal patients' gait/balance; (2): Rescue-strategies after gait-associated disability onset; (A): Stabilizing role; (B): Augmentation role; (C): Replacement role; ML: Machine Learning; DWT: Discrete Wavelet Transform; FFT: Fast Fourier Transform; and HR: Heuristic Rules applied based on an absolute motion error, which was determined by the differences in the target body sway angle (motion generated by a custom software) and the participants' motions (acquired by an IMU). For the binary coding scheme, the vibratory motors were activated when the absolute motion error exceeded  $1^{\circ}$ , and for the continuous code, the intensity of vibrations was continuously modulated as a function of the magnitude of the absolute motion error between  $0^{\circ}$  and  $1^{\circ}$ .

High et al. [25] provided biofeedback when participants swayed overcame 10% over the center of their base of support. In contrast to the other studies, a wearable inertial sensor was not used, and the magnitude of postural sway was estimated using center of pressure path length, velocity, and sway area, measured by a force platform.

In the research article [26], biofeedback was provided when the trunk sway exceeded the antero-posterior or medio-lateral sway threshold, in the corresponding direction of the movement, allowing the patients to correct their posture. The body sway was estimated by two gyroscopes which measured the pitch and roll sway angular. Once the patient body sway crosses the threshold (40% of the ranges of the pitch and roll sway angular), the vibrotactile remained active as long as the threshold was exceeded.

#### 3.3.3 Biofeedback strategies to decrease the risk of falls

Ayena et al. [27] used the sensor measurements (accelerometer and FSRs data) to compute the risk of falling level associated to human balance, and the biofeedback was provided at 10% above the cadence.

Lee et al. [28] provided direction-coded vibrotactile cues, triggered by leg tilt, in order to prompt step generation. The control loop was based on a left leg velocity threshold. A positive angular velocity, produced by forward passive body sway induced by a backward platform translation, triggered the forehead vibrating motor alerting subjects to take a forward step. A negative velocity triggered the occipital vibrating motor.

Faraldo-Garci et al. [29] used a body sway analysis provided by the Vertiguard-RT device (Vesticure GmbH, Germany) to provide biofeedback. The main unit determines continuously the Coriolis force based on gyroscope data and compares those values with individual preset thresholds for stimulator activation in specific directions. Vibrations were reinforced with increasing sway and no feedback was applied if the patient's sway was below preset thresholds.

## 3.4 Validation methodology highlights: participants, criteria study, metrics, and VBS effects

Table 3 summarizes the validation methodology of the selected studies. It highlights the study participants and their evaluation, the inclusion/exclusion criteria, the experimental protocols, the research evaluation metrics, and which effects are observed and measured with VBS. As previously, the VBS categorization proceeded according to the target motor symptoms associated with gait problems.

Hoehn and Yahr scale (H&Y) and Unified Parkinson's Disease Rating Scale (UPDRS) were the most common scales used to produce a comprehensive tool to monitor the degree of disability [20–29]. Thirty-nine-item Parkinson's Disease Questionnaire (PDQ-39) evaluates patients' quality of life, used in [27]. UPDRS-III [20, 27], Postural Instability and Gait Disorder sub-score (PIGD) [20]<sup>,</sup> and Activities-specific Balance Confidence (ABC) scale [26] were used to reflect the evolution of motor function. To indicate the patients' cognitive and mental stage, the Mini Mental State Examination (MMSE) scale was used in [24, 26, 29], Montreal Cognitive Assessment (MoCA) in [20] and Frontal Assessment Battery (FAB) scale in [25]. FOG-questionnaire was used in [22].

Inclusion and exclusion criteria comprised the diagnosis of PD [20, 21, 24–29], specific ON [25, 28, 29] or OFF [20, 21] medication phases, ability to walk independently, non-presence of other neurological diseases, non-presence of musculoskeletal or vestibular disorder, and non-presence of dementia or cognitive damages [20, 21, 24–29]. When studies aimed to mitigate FOG, the presence of this symptom was also an inclusion criterion [20, 21], as well as the bilateral symptoms and impaired postural stability for the balance tests in [24]. Also, specific scores for PD scales were used to include/exclude some participants: MMSE > 24 in [24], MMSE  $\geq$  25 in [28], and H&Y scores of II–IV in [20].

Depending on the applicability of the VBS, each investigation oriented its validation metrics as follows. When the VBS was developed to ameliorate FOG, FOG ratio [20, 21], percentage of freezing time [20, 21, 23]' and number of FOG episodes [23] were the metrics used to evaluate if the patients were able to overcome or prevent a FOG event. In studies [20, 21], it was aimed to evaluate the effectiveness of using VBS in reducing the number of FOG events during turnings. Thus, the velocity of turns and the average number of jerkiness were considered. When the applicability referred to balance improvements, the control variables considered body sway metrics, as limit of stability (LOS), position error (PE) [24], center of position (CoP) path length, CoP velocity [25] and roll/pitch sway angle [26]. If the VBS aim were to reduce the number of falls, besides the index of risk of falling [28] and the number of falls [29], the used metrics intersected with postural metrics, namely the body sway, ABC scale, and standard balance deficit test (SBDT) score [29]. Further, when the experimental protocol was based on Instrumented Timed Up and Go (iTUG) test [29] or the accomplishment of a specific circuit [23, 27], the iTUG time and time to perform the circuit served as metrics to validate their systems. Lastly, Faraldo-Garci et al. [29] used metrics related to cognitive assessments and

Table 3	VBS (	develc	pped over the p	past 10 years to mitigate gait-as	sociated disabilities in PD regardin	ng their clinical highlights		
VBS		PD	participants	Criteria study		Protocol	Metrics	VBS effects
Goal	[Ref.] Year	N	Scales	Inclusion	Exclusion			
FOG	[19]	63 43	- - UPDRS-III; - PIGD score; - MoCA;	- - Diagnosis PD; - w/ FOG; - H&Y scores of II-IV; - Off-phase of medication;	<ul> <li>Other factors affecting gait</li> <li>Inability to stand or walk;</li> <li>Inability to safely walk w/o walking aids;</li> <li>Dementia;</li> </ul>	<ol> <li>T-m iTUG test</li> <li>min turning under single- and double-task</li> <li>Baseline condition: no cue;</li> <li>Closed-loop cueing: phase-dependent feedback;</li> <li>Open-loop cueing: metronome (w/ and w/o cognitive tasks).</li> </ol>	- FOG ratio; - FOG ratio; - % freezing time; - N of tums; - x <sup>=</sup> of velocity; - x <sup>=</sup> of jerkiness of turnings;	FOG ratio; Freezing time; $\downarrow x^{-}$ turns; $\downarrow x^{-}$ turn velocity; $\downarrow x^{-}$ of jerkiness
	[21]	~ ~	- H&Y - UPDRS;	<ul> <li>Idiopathic PD;</li> <li>- w/FOG;</li> <li>- Ability to walk independently;</li> <li>Off-phase of medication;</li> </ul>	<ul> <li>Other neurological disorders;</li> <li>Orthopedic disorders;</li> <li>Other impairments that could interfere w/gait;</li> </ul>	<ol> <li>1 min turning</li> <li>(1) Baseline condition: no cue;</li> <li>(2) Open-loop cueing: metronome;</li> <li>(3) Closed-loop cueing: phase-dependent feedback.</li> </ol>	- % freezing time; - FOG-ratio; - $x^{=}$ of velocity; - $x^{=}$ of jerkiness of turnings;	01 untillings - % freezing time; - FOG-ratio; - $x^{=}$ turn velocity; - $x^{=}$ of jerkiness of turnings
	[22]	∞ v	- H&Y I IDDS.			Walk + 180° turning + climb stairs (1) Baseline condition: no cue; (2) W/ biofeedback.	- Time to norform	- Time to nerform
	<u>[7]</u>	n	- OFDCS, -FOG question- naire;			Curcutt. (1) walk; (2) turn; (3) walk along a carpet; (4) turn; (5) walk around a chair and sit on it (6).	<ul> <li>Tune to periodit the circuit;</li> <li>N of FOG episodes;</li> <li>-% freezing time:</li> </ul>	<ul> <li>Time to pertoning the circuit;</li> <li>N of FOG episodes;</li> <li>- % freezing time:</li> </ul>
Balance	[24]	6	- H&Y - MMSE;	- Idiopathic PD; - Bilateral symptoms; - Impaired postural stability;	<ul> <li>- MMSE score &gt; 24;</li> <li>- Not ready for physical activity;</li> <li>- Dyskinesia;</li> <li>- Severe distal sensory loss;</li> <li>- Medically unstable;</li> <li>- Other neurological or nusculoskeletal conditions;</li> </ul>	Dynamic weight-shifting balance exercises: (1) Two coding schemes; (2) Two movement directions.	- LOS - Position error;	- LOS improvements - Position Error;
	[25]	6	- UPDRS;	- On-phase of medication;		<ol> <li>30 sec quiet standing</li> <li>(1) eyes open/closed;</li> <li>(2) firm/foam surface w' and w/o biofeedback.</li> </ol>	<ul> <li>CoP Path length</li> <li>CoP Velocity</li> <li>Sway area</li> </ul>	- ↓CoP Path length - ↓CoP Velocity - ↑Sway area
	[26]	20	- H&Y - UPDRS; - ABC; - MMSE; - FAB;	- On-phase of medication;	<ul> <li>Other non-PD causes of balance impairment;</li> <li>Inability to walk w/o walking aids;</li> <li>Cognitive or psychiatric distubances;</li> <li>Comodridity:</li> </ul>	Pre-training: gait & stance tasks; (1) Training: balance exercises; (2) Pos-training: gait & stance tasks.	- Roll/Pitch sway angle;	- JRoll/Pitch sway angle;
Falls	[27]	12	- H&Y - UPDRS-III; - PDQ-39;	<ul> <li>Ability to walk over different surfaces;</li> <li>Adequate vision</li> <li>Hearing acuity;</li> <li>Somatosensory perception of the lower limb;</li> </ul>	<ul> <li>Cognitive impainments;</li> <li>Uncontrolled health;</li> <li>Other neurological disorders;</li> <li>Comorbidity;</li> </ul>	iTUG test: (1) Baseline condition: no cue (2) Other types of soil: no cue (3) Other types of soil: w/ feedback.	- Index of risk falling - iTUG time	- JIndex of risk falling: - JiTUG time;
	[28]	27	- Н&Ү;	- On-phase of medication;		Computer-controlled platform training: (1) Baseline condition: no cue; (2) Randomized backward/forward translations: w/ feedback.	<ul> <li>Reaction time;</li> <li>Step length;</li> <li>Trunk</li> <li>displacement;</li> </ul>	(backward) - JReaction time; - JStep length; - JTrunk disensent*
	[29]	10	- H&Y - MMSE.	- On-phase of medication.	- Use of wheelchair; - Additional neurological	SBDT tasks: (1) Baseline condition: no cue;	- $x^{=}$ value of body sway	- thody sway;

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VBS	PD participants	Criteria study		Protocol	Metrics	VBS effects
Goal [Re Yea	[] N Scales	Inclusion	Exclusion	I		
			Deficits; - Dementia; - MMSE ≥ 25; - History of peripheral vestibul¢ disease.	(2) W/ biofeedback.	- SBDT; - SOT score; - DHI questionnaire; - ABC; - N of falls.	<ul> <li>SBDT not significant</li> <li>SOT improvements</li> <li>JDHI scores,</li> <li>ABC</li> <li>ABC</li> <li>ABL</li> <li>ABL</li> <li>ABL</li> </ul>

sensory perception, Dizziness Handicap Inventory (DHI) score, and Sensory Organization Test (SOT) score, respectively.

Mancini et al. [20] studied the effectiveness of open-/ closed-loop cueing in alleviating FOG during turnings. Participants turned in place for 1 min under single- and dualtask (ST and DT) for three randomized conditions: baseline, turning to the beat of a metronome (open-loop), and turning with phase-dependent tactile biofeedback (closed-loop). To objectively characterize freezing and turning for each condition, they estimated the (i) FOG ratio (power spectral density ratio between high and low frequencies of antero-posterior shins accelerations), (ii) the percentage of time spent freezing, (iii) the number of turns, (iv) the average turn peak velocity, and (v) the average jerkiness of the turns. Number of turns and the average turn peak velocity were computed through the yaw angular velocity of trunk. Both open- and closed-loop cueing significantly reduced FOG: for example, FOG ratio significantly improved when turning with both open-loop (0.9) and closed-loop (1.1) cueing compared to baseline (6.7) sessions. The same pattern was observed for the percentage of time spent freezing, a decrease was obtained from 42% (ST) and 33.9% (DT) at baseline to 18% (ST) and 18% (DT) for open-loop cueing and to 19% (ST) and 18% (DT) for the closed-loop cueing. Further, both open- and closed-loop cueing significantly improved turning smoothness since they achieved a reduction in the number of turns, the average turns peak velocity, and the average jerkiness of the turns from the baseline session. DT did not worsen FOG, but significantly reduced velocity of turns.

A similar methodology was followed by Harrington et al. [21]: the effects of biofeedback were studied to mitigate FOG during turnings. Participants performed a course with turnings for 1 min under three conditions: turning without any external cue (baseline session), turning to the beat of a metronome (control condition), and turning with phase-dependent tactile biofeedback (biofeedback condition). FOG ratio was one of the evaluated metrics and reduced from 2.5 at baseline to 1.4 for control condition and 1.0 for the biofeedback condition. The percentage of time spent freezing was also measured and significantly decreased from 48% at baseline to 25% in the control condition and to 19% in the biofeedback condition. Unlike Mancini et al. [20], the average turn peak velocity and jerkiness did not show a significant difference among the three conditions.

Cando et al. [23] evaluated the effectiveness of biofeedback to overcome FOG over a walking circuit designed to provoke freezing events, which included turnings, walk through a carpet, circumvent obstacles, and sit. Participants performed the circuit under two conditions, with and without biofeedback. The average time to perform the complete circuit was measured and it was obtained an improvement from 146 to 96 s when applying biofeedback, a decrease of 34%. Also, the number of FOG episodes was evaluated, and a reduction was obtained from 11 to 8, achieving an improvement of 27.27%.

Lee et al. [24] explored the effects of two coding schemes (binary vs continuous) of vibrotactile cues during dynamic weight-shifting exercises. To characterize participants' ability to perform the balance exercises as a function of the coding scheme and movement direction, three metrics were computed for each trial: LOS and PE. PE is computed as an average absolute difference between the target and participant's movements. This study revealed that all of participants significantly improved LOS in both antero-posterior and medio-lateral direction and less PE with the continuous coding scheme than with the binary coding scheme.

High et al. [25] intended to study how the vibrotactile biofeedback can alter the dynamics of static postural control. Thus, participants performed 30-s quiet standing on a force platform under five challenging stance conditions with eyes open/closed and standing on firm/foam surface, each with and without vibrotactile feedback. Results revealed that vibrotactile feedback induced a change in postural control dynamics among participants, being observed a decrease on the distance and mean velocity travelled by CoP, and an increase on the sway area for the trials with biofeedback.

Nanhoe-Mahabier et al. [26] verified the effects of biofeedback in trunk sway. All participants performed (1) two sets of six gait tasks and six stance tasks (pre-training assessment); (2) six selected tasks five times (balance training); and (3) a repetition of the balance training tasks (post-training assessment). For the experimental tests, it included a control group of participants, who did not receive biofeedback, and a study group, who received vibrotactile cues in pre-training and posttraining assessment. During all tasks, sway angle and sway angular velocity were measured for pitch and roll plane. A significant reduction in these metrics was achieved for the group that received biofeedback.

Ayena et al. [27] analyzed how biofeedback affect the risk of falling while walking on six types of soil (concrete, sand, parquet, broken stone, two types of carpet). Thus, participants performed an iTUG test with and without cueing and it computed a new index of risk of falling, which was expressed by the coefficient variation of gait parameters. The results suggested a significant decrease in the computed risk of falling and iTUG time for most of types of soil, especially for deformable soils, which can lead to falls.

Lee et al. [28] aimed to characterize the stepping responses to unpredictable forward/backward postural perturbation and assess whether vibrotactile cues can improve the stepping response. Participants stood on a platform moving unpredictably forward and backward, requiring a protective step to maintain balance. Direction-coded vibrotactile cues, triggered by leg tilt, were provided to prompt step generation. They verified that all subjects showed quicker reaction times, shorter steps, and smaller total trunk displacement when applying biofeedback.

Faraldo-Garci et al. [29] proposed a study to assess the effectiveness of balance training with a vibrotactile biofeedback to improve patient stability. Thus, participants performed a body sway analysis of stance and gait tasks (SBDT) and their postural stability was assessed by Sensory Organization Test (SOT), Dizziness Handicap Inventory (DHI), activityspecific balance confidence scale, and the number of falls over the past 3 months. They obtained a significant improvement in body sway, number of falls, and scores of SOT and DHI tests, in the biofeedback training sessions.

#### 3.5 Methodological quality assessment

Only six studies [22, 24–28] performed a case-control study, which were submitted to the CASP checklist. CASP checklist is divided into three sections: Section A ("Are the results of the study valid?"), Section B ("What are the results?"), and Section C ("Will the results help locally?").

In order to find a common interpretation for each of the items evaluated in Section A, the following hint-questions were used to determine positive/negative scores, as proposed by CASP-checklist: "Does the control group consist of subjects with the same condition?" "Is the number of subjects in each group equal?" "Were the groups randomly selected?" "Did all participants perform the same test conditions?". It was considered positive if the study included a control group with a different specific condition (with/without PD), presented a matched gender/age, the groups were composed by the same number of participants and were randomly asserted, and if they performed the same test conditions. Five studies included age-matched healthy control groups [24-28] and only three studies presented the same number of case control groups [24–26], and only one study randomly selected the control group.

Section B assesses three key points: (1) how large is the treatment effect, (2) how precise was the estimate of the treatment effect, and (3) if the reader believes in the results. As previously, it used CASP-based hint-questions to obtain a less subjective appraisal: "How strong is the association between exposure and outcomes?" "Do the experimental tests allow to evaluate the objectives of the studies?" "Are the outcome measurement objective?" and "Is the analysis appropriate to the design study?". All studies showed strong correlations between the treatment effect and the use of vibrotactile biofeedback, i.e., the patients presented improvements at the level of their motor performance in the clinical trials with the use of VBS. Also, all studies presented experimental tests which enabled to assess the research questions. Three studies could present more measurement outcomes to obtain more realistic results [22, 24, 27]. An appropriated statistical analysis was adopted by all studies [22, 24-28].

All studies fulfilled the items of Section C, since the results, obtained in the target population, can be replicable and extensible. To evaluate the replicability of the studies, it was verified whether the studies covered variables that allow inferring that the results were reliable for a different local set [22, 24–28].

#### **4** Discussion

# 4.1 Which are the technologies integrated in VBS, what are their setting parameters, and where are they placed?

VBS makes use of electronic equipment to provide the user additional sensory information, beyond the one naturally available to him [16]. Consequently, it was identified that VBS comprises an actuation system, a sensory system, and a main-control unit.

The actuators most used are the ERM motors [19, 22, 23, 25–29], due to their small size, enclosed vibration mechanism, low-power consumption, these vibrating motors are a common choice for wearable systems [31]. Limitations of ERM motors include latency in starting and stopping and it is not possible to control vibratory amplitude and frequency independently.

Research aiming to study the effects of biofeedback to improve balance [24–26] used more actuators (mostly eight around the waist). On the other hand, research aiming to mitigate the FOG [19–23] or reduce the risk of fall [27–29] used fewer actuators. The number of vibrotactile units is a determining factor for human perception of vibrotactile signs. Indeed, Cholewiak et al. [32] studied the main conditions for the precise location of vibration stimuli applied around the abdomen. They verified that by reducing the number of units, the percentage of vibrotactile cue detection increases since it requires lesser cognitive effort. Therefore, it is needed to find a compromise between the number of vibrating motors to be used and the patients vibrotactile perception [25, 26], so as not to become cogently burdensome to discriminate spatial vibratory information [32].

All studies used a range of frequencies within the human perception range (80–300 Hz) [30] and it was found that there is a tendency to use higher frequencies ( $\geq 250$  Hz) [20, 21, 23, 24, 26, 29], especially for systems used to mitigate FOG. However, no study considered that the nerve impulse degrades progressively in each neuronal "level" until it reaches the cerebral cortex, due to a progressive decrease of the "firing" frequency [33, 34]. The cerebral cortex, more precisely the somatosensory cortex, becomes saturated when it reaches a plateau of relatively low frequencies [33]. Thus, it is necessary to distinguish the perceptual capacity of the mechanical receptors in the skin and the discrimination capacity of the

sensorial information of the cerebral cortex, relative to the somatosensory system. Hence, although the skin can achieve vibration detection thresholds between 80 and 300 Hz, the cerebral cortex only discriminates frequencies between 80 and 250 Hz [33]. Thus, [20, 21, 23] used vibration frequencies above 250 Hz, which may not have been discriminated at the cerebral cortex level. However, this discrimination may not be significant when the objective of the vibrotactile biofeedback system is only to provide an "alert" cueing and not to provide orientation information. That is, in Cando et al. [23], the vibrotactile cues were used as a rescue strategy from the event of FOG, not being significant the vibratory discrimination at the cortex level. But, in studies [20, 21], the vibrotactile cueing was used to be associated with the gait phase stance in order to re-integrate the controlled gait pattern into the patients' motor system, where discrimination of vibratory frequencies at the level of the cerebral cortex is already important [33, 34].

Making use of front-end miniaturized technology, IMUs were the most frequent sensors used to be integrated on the sensory systems of the VBS [19–24, 27]. They provide information from their integrated accelerometer, gyroscope, and magnetometer. They are an appropriate solution to record on-body inertial information given their low-power consumption, portable and easily integrated on wearable devices [35].

The processing units used were usually miniaturized (smartphones and Arduino boards), offering greater portability to devices and facility of use in contexts close to daily life. However, the use of computers in studies [23, 25] constrains the applicability of their solutions to dedicated environments and for the single purpose of rehabilitation. Disadvantageously, these systems force patients to travel to the locations where these devices can be used. In summary, the studies from [19-22, 27, 28] could have applicability for daily situations. Particularly, Mikos et al. [19] used a FPGA, which allows to have high computational performance in a miniaturize and portable board. In fact, it is the only system that ran a real-time machine-learning algorithm (Table 2), contrasting with other systems that have implemented in most algorithms based on heuristic methods. In general, it is found that devices that have used a computer as a processor were designed to be used for motor rehabilitation contexts [23, 25], while devices developed to mitigate FOG and only [27, 29], developed to improve balance and reduce the risk of falling, which used miniaturized and portable boards, intended to be used for daily walking situations. Therefore, the choice of the processing unit must be identified based on the purpose of use.

Regarding the location of actuators and sensors, it was considered important to discuss their location regarding the wearability of the systems. For instance, by analyzing Fig. 3, it is indicated that there is not a common body zone to place the vibratory motors, but could be reasonable to indicate that the ankle zone is indicated to place the sensory system [19, 22, 23, 27]. However, only the studies [19, 22] positioned the actuation system also on the ankle. Indeed, in [20, 21, 25, 26, 28], the sensors and actuators were placed on different body zones, not presenting a VBS comprised by a singleone wearable device compromising its usability. In addition, when discussing the location of actuators and sensors regarding their disease-associated applicability, it observed a pattern. When the applicability of the systems is to mitigate the FOG, the ankle zone was elected for both actuator and sensory system location [19, 22]. On the other hand, when it is intended to provide sensory cueing information about users' balance or to reduce the number of falls, the trunk area, more precisely at waist level, was preferable for placing the actuation system [24, 25] and the sensory system [24, 26]. Therefore, the location of the electronic components, besides should be integrated on a single device, should be adapted to the intended use regarding the target motor symptom.

#### 4.2 How have the biofeedback loops been applied in VBS to mitigate parkinsonian gait-associated disabilities?

Most of the identified VBS implemented biofeedback loops that provide rescue strategies to help patients overcome some identified gait-associated disability [19, 22-26, 28, 29]: "When a FOG event occurs", "when participants swayed overcome 10% over their center of mass", "when 40% of the ranges of the participants pitch and roll sway angular",

of the actuators and sensors

vibrotactile biofeedback is provided. This approach enabled positive effects, being verified that all research metrics improved. However, this biofeedback loop is applied after the gait-associated disability occurs, not preventing its occurrence. To overcome this, another type of biofeedback strategy may be considered. Indeed, studies [20, 21, 27] applied phasedependent vibrotactile biofeedback, where vibrotactile stimuli are employed during a predetermined phase (e.g., stance phase) in order to re-integrate the biofeedback into the patients' motor system, as an augmentation rule to maintain controlled motor behavior and avoid gait-associated disabilities.

Although many studies have already tried to understand the underlying role of biofeedback application (stabilizing role, augmentation role, or replacement role), there is no clear definition of which biofeedback strategies most benefit patients or should be specified for a certain motor disability [14]. However, we observed that devices used to assist patients while walking tend to provide onset vibrotactile cues (replacement role), as in [20, 21, 27], aiming to help patients to not suffer from FOG and avoid falling. Devices used during rehabilitation, as in [24-26, 28, 29], are often associated with typical posture and gait exercises to increase the rehabilitative power and instruct patients to correct or mitigate their motor symptoms (stabilizing and augmentation role). Nevertheless, further studies are needed to clarify whether there is a type of sensory cues suitable to mitigate a particular motor symptom or to be applied in certain environment.



#### 4.3 How have the VBS been clinically validated?

The clinical protocols usually comprise two-main trials: (1) a baseline session, without providing biofeedback, and (2) a biofeedback session, where it provided the feedback. Further, in [20, 21]' it studied closed-loop vs open-loop cueing strategies, i.e., the biofeedback trials comprise a session with phase-dependent vibrotactile biofeedback and a fixed metronome feedback.

It is highlighted that all studies applied to overcome FOG involved gait tasks: walking in straight line, turning, and climbing stairs [19–23]. In the other studies [24–26, 28, 29], participants performed specific balance exercises, excepting in [27], which also involved gait tasks, particularly with different type of soils.

Mancini et al. [20] considered another variable that can affect motor tasks: participants performed gait tasks with and without concurrent cognitive tasks (dual-task condition). This test condition not only reveals whether performing one more task can affect the perception of sensory cues, but also addresses everyday multitasking situations.

No study was validated on home-based conditions, not reliably repeating the daily tasks of patients. The inclusion of these tasks, such as lifting bags (e.g., in a supermarket), walking in narrow places, or walking in stairs/ramps, would benefit patients in terms of motor assistance and rehabilitation by considering functional tasks more similar to their daily context. Also, the systems validation should be more personalized and user-centered, which would allow system functionalities to address users' requirements (such as use of sensory cueing easily perceived without requiring cognitive demands, application of more lightweight technologies, or implementation of unobtrusive devices). Further, the identified studies evaluated the effectiveness of their systems comparing patients' motor behaviors in sessions with and without biofeedback (baseline condition vs sensory-cueing driven condition). However, it is important to perform long-term retention tests to evaluate the sensory cueing integration on patients' motor systems, after an extensive period of usage.

Despite the low clinical evidence, the number of participants with PD has been increasing recently [19, 20]. However, there is still a need for further clinical evidence. Based on the scales used by the researchers to monitor patients' disease degree, it is possible to organize them as (1) clinical assessments-UPDRS, H&Y, FOG-questionnaires, 39-PDQ; (2) cognitive assessments-MoCA, MMSE, FAB test; and (3) motor assessments—PIGD, ABC, UPDRS-III [20-29]. Indeed, a complete evaluation of PD participants must include these three types of assessments [16]. Additionally, the study criteria for the participant selection should consider the same evaluation, and, ideally, all external factors that may affect participants' motor functions should be eliminated, as, other motor conditions, and cognitive impairments. Lastly, only studies [23-26] considered an age-matched control group constituted by the same number of participants and submitted to the same test conditions.

In order to evaluate the effects of an intervention, a control study design is indicated [18], and considered in [19–21, 23, 29]. The studies that followed this design study were submitted to the CASP checklist [22, 24–28]. However, these studies may have a limited validity since the majority did not perform a random selection of study groups and did not include the same number of participants, which can affect statistical analysis. Even so, the experimental tests carried out allowed to answer the identified research questions, and the study metrics were properly and logically applied and statistically analyzed, obtaining results that can be extensible for a different local set. However, these studies will benefit from larger replicability and extensibility in the target population, by including daily tasks in the experimental tests, like walking in narrow places, crossing doors, or walking in stairs/ramp, even if keeping the same study metrics.

Results regarding the biofeedback effects in gait-associated disabilities were very positive when using biofeedback both to mitigate FOG and to improve postural control and prevent falls. However, from the users' point of view, some gaps were still found. The VBS from studies [23, 27] were integrated into footwear, which limit the choice of the user's footwear. In addition, in the work [27], some patients claimed to have a low perception (almost none) of the vibrations in the foot area. On the other hand, regarding comfort issues, Lee P. et al. [28] used a band with the actuators for the head, which can be annoying. Likewise, the systems that provided the biofeedback in the trunk area used a considerable number of actuators, which in terms of reproducibility for the user quotidian may require some cognitive effort to perceive the spatial pattern of vibration. Finally, no system carried out a usability questionnaire and evaluated the patients' acceptability of the devices used. In order to develop a system that aims to maximize users' benefits, these concerns should be addressed and drive a user-centered design.

#### 4.4 Limitations and future directions

We observed that there is still a need to develop more robust VBS that can integrate all their components into one single device to facilitate its usability. It is required to reduce the number of actuators in some studies, so as not to become cogently burdensome to discriminate spatial vibratory information. Also, future studies should consider the frequency range of human perception taking into account the sensorimotor system perception, as also the vibration discrimination at the cortex level. The location of the sensors should be the same as that of the actuators in order to contribute to the portable and comfort character expected in these systems. Most of the VBS provided vibrotactile biofeedback as a stabilizing or a replacement role, that is, the vibrotactile cueing was delivered during or after the gait-associated disability occurrence, not preventing its occurrence. More studies are required to understand how the biofeedback should be applied

for each motor condition or even if there is a biofeedback role with more efficiency. The validation methodology was performed in controlled environments and, consequently, these systems need to be validated on settings which integrate patients' daily lives challenges. These will enable more personalized treatments. Also, it is required to perform usability tests to assess the level of acceptability of VBS.

Taking all this in mind, we identified the following future challenges, unanswered research questions: VBS should integrate all their subsystems into a single device, in order to overcome wearability issues; VBS should be able to be used in patients' daily lives, considering ergonomic and comfort requirements; VBS should address these two objectives (1) preserve optimal patient's gait/balance control and (2) implement rescue strategies, in order to deploy the most suitable strategy for each motor symptom; VBS should include more clinical evidence; usability tests should be assessed and drive a user-centered design able to include the endusers' requirements in the VBS design process; realize a long-term retention test to evaluate the motor re-integration after applying biofeedback; and VBS effects should be correlated with the clinical, cognitive, and motor/sensory assessments.

Table 4 summarizes all identified limitations regarding technological, adopted biofeedback strategy, and validation methodology issues. It highlights the affected users' requirements and provides guidelines for their mitigation based on the proposed model by Hagedorn et al. [36], to support usercentered design of medical devices.

#### **5** Conclusions

By reviewing the current state-of-the art of vibrotactile biofeedback devices for PD, it is verified that these systems are essentially oriented to the symptom of FOG. There is prevalence to apply miniaturized wearable actuators and sensors, namely, ERM motors, attached to the user's head, waist, insole, or ankle; and IMUs placed on patients' waist and ankle. Overall, most systems did not used a one-single device, making the systems more intrusive and weightless, increasing usability issues. Regarding the control system, responsible to measure, detect, and generate the intended vibrotactile responses, heuristic computation was the methodology most adopted. Also, it was observed that most studies implemented a biofeedback loop able to provide rescue strategies after the detection of a gait-associated disability. Despite the great scientific contribution for PD to overcome gait-associated disabilities of the reviewed studies, it is necessary to obtain more clinical evidence and implement experimental sessions to evaluate if the biofeedback was integrated into the patients' motor system. Finally, through the reported effects of the VBS, it can be concluded that they are a promising tool to ameliorate FOG, increase the postural stability, and decrease the risk of falling.

 Table 4
 Identified limitations of current VBS applied to mitigate gait-associated disabilities in PD and affected end-users' requirements and guidelines for their mitigation based on a user-centered approach

	Limitations	End-users' requirements	Guidelines based on user-centered approach
Technology supporting	$\pmb{X}$ Sensors/actuators with different body location	Portability, comfort	<ul> <li>✓ Place all technological components on a single device.</li> <li>✓ Preferable use of wearable and miniaturized technology.</li> </ul>
VBS Biofeedback strategies	$\pmb{\varkappa}$ Increased number of actuators and not consideration of human vibratory perception	Low cognitive demands for vibratory perception	✓ Decrease the number of actuators and adjust the vibratory frequencies range considering the sensorimotor system perception.
	✗ No clear definition of how biofeedback should be applied considering the different motor symptoms	Gait performance improvements	✓ Explore the application of biofeedback to preserve optimal patient's gait/balance control and implement rescue strategies.
Validation methodology	<b>X</b> Experimental tests in controlled environments and without addressing daily motor tasks	Personalized treatments	✓ Perform experimental tests in home-based scenarios addressing daily motor tasks.
highlights	<b>X</b> Limited methodology validation	Effective intervention	<ul> <li>✓ Include age-matched groups and randomly selected.</li> <li>✓ Include the same number of participants between study groups.</li> <li>✓ More clinical evidence.</li> <li>✓ Include a long-term retention test.</li> <li>✓ Statistical analysis that relates biofeedback effects with clinic/motor-related scales</li> </ul>
	$\pmb{X}$ No accomplishment of usability tests	Device's acceptability	<ul> <li>✓ Accomplishment of usability tests and re-validation.</li> <li>✓ Devices re-assessment and inclusion of new features driven by users' needs (stakeholders brainstorming).</li> <li>✓ Inclusion of user' opinion for devices development (requirement questionnaires).</li> </ul>

Author contribution Cristina P. Santos had the idea for the manuscript, all authors performed the literature search and data analysis, Helena R. Gonçalves drafted the original article, and all authors critically revised the work.

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#### Declarations

**Conflict of interest** The authors declare no competing interests.

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Helena R. Gonçalves received a MSc degree in Biomedical Engineering with specialization in Medical Electronics in 2017, from the University of Minho, Portugal. Her master thesis covered the development of a wearable vibrotactile biofeedback device for patients with Parkinson's Disease. She is currently a Ph.D. student in Biomedical Engineering in University of Minho and a researcher from the Center for MicroElectroMechanical Systems, with a closed collaboration with

Clinical Academic Center at Hospital of Braga. Her investigation aims to design and implement high technologies based on personalized sensory cueing biofeedback strategies to assist patients with Parkinson's Disease to mitigate gait-associated abnormalities. Her research interests focus on usercentered wearable devices, neuroscience, gait analysis and AI-based systems to analyze motor symptoms in Parkinson's Disease.



Ana Margarida Rodrigues is a neurologist at Braga Hospital specialized in movement disorders. Graduated in Medicine in 2005 in Instituto de Ciências Biomedicas Abel Salazar, and finished neurology residency at Braga Hospital in 2011. During residency, underwent training in Movement Disorders at Hospital de S. Joao Movement Disorders Unit and at Hospital das clinicas – UFMG. Currently responsible for movement disorders and botulinum toxin outpatient clinics, and

for medical education of neurology residents in movement disorders, residents of other medical areas and medical students. Also, she is neurology teacher at Escola de Enfermagem, at Minho University. Margarida cooperated with "Escola de Medicina" at Minho University, ICVS- Life and Health Sciences research and Biomedical Engineering, developing many investigation projects specially in Parkinson's disease. Recently, she is vice-president of Portuguese Movement Disorders Society (2019-2021).



Cristina P. Santos Graduated in Industrial Electronics Engineering in 1994, received the M.Sc. degree in 1998 and the Ph.D. degree in 2003, all from the University of Minho, Guimarães, Portugal. Her PhD thesis work was in cooperation with the Centre National de Recherche Scientific(CNRS-CNRC) Marseille, France. She is an Auxiliar Professor at the University of Minho, Industrial Electronics Department, Portugal. She was the principal in-

vestigator of more than 10 research projects in the areas of Robotics and Artificial Intelligence, in particular, locomotion field and rehabilitation. She is currently supervising 8 PhD thesis and has supervised 40 MSc thesis to completion. She is the author of more than 100 publications in ISI and Scopus international conferences and journals. Her research focus on the extension of the use of the dynamical systems theory to the achievement of more complex behavior for robots: generate locomotion for multi-dof robots; achieve cooperativity among multi-robots and learning. Recently her research interests focus on methods to characterize human motion and designing robots, and robot controllers for the rehabilitation of patients suffering from motor problems.