1	Title: Lower limb somatosensory discrimination is impaired in people with Parkinson's disease:
2	novel assessment and associations with balance, gait and falls.
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### 27 Abstract

28 Background: People with Parkinson's disease (PD) often have compromised walking and balance.

29 This may be due to impaired lower limb tactile and proprioceptive sensation. Existing clinical

30 measures may not be sufficiently sensitive to uncover these sensory impairments.

31 Objective: Determine whether novel measures of lower limb somatosensory discrimination are

32 psychometrically robust and associated with mobility outcomes in people with PD.

33 Methods. Lower limb somatosensation was assessed on two occasions, 3-7 days apart, using three

34 novel tests: gradient discrimination, roughness discrimination, and step height discrimination. Static

35 and dynamic balance (Brief Balance Evaluations Systems Test), falls incidence, falls confidence

36 (Falls Efficacy Scale), gait (speed and step length) were also obtained. Participants were twenty-

37 seven people with PD and twenty-seven healthy controls (HC).

38 Results: Novel tests showed good-excellent intra-rater reliability (ICC=0.72-0.92). Significantly

39 higher gradient and step height discrimination thresholds (p<0.01) were demonstrated in PD

40 compared to HC, indicating worse position sense at the ankle, knee and hip. Significant correlations

41 were identified between gradient discrimination and falls incidence (r=0.55), falls confidence

42 (r=0.44), balance (r=0.63), but not gait (r=0.21). Step height discrimination was significantly

43 correlated with balance (r=0.54). Foot roughness discrimination was not significantly different

between people with PD and HC and was not significantly correlated with mobility measures

45 (p>0.05).

46 Conclusion: These novel tests are psychometrically robust and identify impaired lower limb position
47 sense which were associated with balance and falls in this sample of PD. Interventions targeting
48 somatosensory processing in PD may improve aspects of balance and reduce falls risk. Further
49 research is warranted.

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### 52 Introduction

Parkinson's disease (PD) is the second-most common neurodegenerative disease after
dementia.<sup>1</sup> It is a progressive neurological condition characterised by both motor and non-motor
symptoms with many clinical symptoms related to difficulties with movement. Such difficulties often
lead to postural instability, reductions in walking ability and impaired balance which negatively
impact participation in activities of daily living, quality of life and falls.<sup>2,3</sup>

58 The view that movement difficulties in people with Parkinson's disease (PD) are attributable purely to motor deficits has been challenged in recent years by evidence of impaired processing and 59 integration of somatosensory information<sup>4</sup>. Tactile and proprioceptive sense, referred to as 60 somatosensation, arise from sensory receptors in skin, joints, tendons, and muscles providing 61 feedback of an individual's body position, body and limb motion, and interaction with the 62 environment.<sup>5</sup> Studies have shown people with PD to have deficits in somatosensory processing such 63 as elevated thresholds to spatial and temporal stimuli,<sup>4</sup> diminished proprioceptive and position sense 64 awareness,<sup>6,7</sup> and impaired haptic sensation.<sup>8</sup> Moreover, when visual feedback cannot be used, 65 people with PD lack precision in their stepping,<sup>9</sup> show greater errors in obstacle clearance,<sup>10</sup> and have 66 67 greater difficulty controlling postural orientation on the basis of available somatosensory and 68 vestibular information compared to healthy controls<sup>11</sup>. Unsurprisingly, deficits in lower limb 69 proprioception are significantly associated with falls incidence in people with PD.<sup>7</sup> It is feasible to 70 posit that sensory deficits may contribute to many of the movement and balance difficulties which are 71 the hallmark of PD. Accurately identifying and quantifying the severity of lower limb somatosensory 72 abnormalities and, crucially, how they are associated with activity and participation limitations 73 represents an important goal to inform rehabilitation interventions.

Several measures of somatosensory function have been evaluated and reviewed<sup>12</sup> in
neurological populations, with the Erasmus MC modified Nottingham Sensory Assessment
(EmNSA)<sup>13</sup>, and the sensory scale of the Fugl-Meyer Assessment<sup>14</sup> suggested to provide the best
balance of clinical utility and psychometric robustness<sup>12</sup>. Those measures, however, have been widely
criticised for largely assessing the detection of stimuli - the lowest level of sensory processing<sup>15</sup>, not

79 providing functionally meaningful somatosensory data, and being insufficient for uncovering the complexities of somatosensory perception<sup>4,16,17</sup>. Furthermore, they have not been evaluated in people 80 with PD. A recent review of proprioception assessment methods<sup>18</sup> highlights a concerning paradox: 81 82 measures which possess clinical utility lack accuracy, whilst those which possess accuracy lack 83 clinical utility. More complex tests of tactile sensation and proprioceptive function such as matching one or more standardised sensations to another, integrating sensation with motor output or 84 distinguishing the temporal or spatial qualities of two stimuli have been shown to uncover 85 somatosensory dysfunction in Parkinson's, yet are largely limited to the laboratory setting.<sup>4,6</sup> In 86 response to the perceived shortcomings of existing clinical measures, we developed three novel and 87 functionally oriented tests of somatosensory discrimination: the Foot Roughness Discrimination Test 88 (FoRDT<sup>TM</sup>), the Step height Discrimination Test (StepDT<sup>TM</sup>) and the Gradient Discrimination Test 89 90 (GradDT<sup>TM</sup>). These functionally oriented tests have been described and evaluated previously in a stroke population<sup>19,20</sup> showing superior psychometric properties to the clinically feasible and 91 psychometrically robust sensory measure the Erasmus MC modified version of the Nottingham 92 Sensory Assessment (EmNSA).<sup>13</sup> To date, however, our novel tests have not been evaluated in people 93 94 with PD.

The aim of this study was to evaluate the psychometric properties of these novel somatosensory measures in people with PD, and report on their associations with clinical measures of gait, balance and falls. Specific objectives were to evaluate intra-rater reliability of the novel measures and convergent and known-group validity. Further, we wished to explore the association between our novel measures with functional measures of gait, balance and falls in people with PD.

100 Method

### 101 **Participants**

We recruited a convenience sample of 27 people with PD and 27 age matched healthy
controls. People with PD were identified through local branches of Parkinson's UK (a UK charity)
and healthy age matched controls were recruited through the University of the 3<sup>rd</sup> Age (a UK

105 volunteer-led organisation providing educational and leisure opportunities to retired/semi-retired 106 individuals). Inclusion criteria were: ability to provide informed consent, walk 10 meters unsupervised (with or without a walking aid), have no have significant cognitive impairment ( $\geq 24/30$ 107 Mini Mental State Examination, MMSE)<sup>21</sup> or comorbidities known to affect somatosensation (e.g. 108 109 diabetic neuropathy). Age matched control participants were included providing they had no pathological conditions known to affect balance, mobility or sensation. Sample size calculations<sup>22</sup> 110 indicated a sample size  $\geq 27$  per group was sufficient for: a 95% CI of 0.25 and a planned ICC of 0.8 111 112 ( $\alpha$ =0.05); detecting a correlation coefficient of 0.29 (power=0.85,  $\alpha$ =0.05); and effect size of 0.79 (power=0.85, α=0.05). 113

# 114 Procedures

Ethical approval was obtained from the University of Plymouth, Faculty of Health and Human Sciences Research Ethics Committee (ref: 17/18-86). People with PD (n=27) were tested with the novel sensory measures on two occasions, between 3-7 days apart at the same time of day and in their self-reported ON state; that is the state in which they felt they were optimally responsive to their medication. The first author was the rater on test session 1 and test session 2. Control participants (n=27) were tested with the novel measures on just one occasion.

Participant demographic characteristics (age, gender) and in the case of people with PD, time
 since diagnosis, upper and lower limb motor function (Movement Disorder Society - Unified
 Parkinson's Disease Rating Scale motor score Part III (MDS –UPDRS III)<sup>23</sup> was collected. Alongside
 the somatosensory tests a range of different health constructs were measured, described below.

### 125 Outcome measures:

The *EmNSA<sup>13</sup>* was used to determine convergent validity of our novel tests. It is considered to be a psychometrically robust and clinically feasible assessment tool<sup>12</sup> involving the assessment of exteroceptive sensation (light touch, pressure touch, and pin-prick), higher cortical discriminatory sensation (sharp-blunt) and proprioception (movement detection and discrimination). 130 The Gradient Discrimination Test (GradDT<sup>TM</sup>) evaluates sensory-perceptual ability to discriminate underfoot surface gradient or slope during standing. It has been described previously and 131 shown to be reliable and valid in a stroke population.<sup>20</sup> It utilises a two alternative forced choice 132 paradigm (2AFC),<sup>24</sup> in which two differing sloping platforms, a base and a comparator, are mentally 133 134 compared (discriminated). The test procedure involves participants standing on a series of adjustable sloping platforms until a discrimination threshold is reached (i.e. the point at which the participant 135 cannot discriminate between two different slopes). This provides a discrimination threshold in degrees 136 (°). The test takes 7-10 minutes to complete. 137

The Step height Discrimination Test (StepDT<sup>™</sup>) utilises the 2AFC approach as detailed above and has been described and psychometrically evaluated previously in stroke.<sup>20</sup> This test assesses an individual's ability to discriminate the height of a step, through lower limb position sense, without visual feedback. The test involves the passive placement of the test limb onto a series of adjustable steps. The 2AFC test procedure involves increasingly difficult trials until the point at which the individual cannot consistently discriminate which of the two presented steps is highest. This provides a discrimination threshold in centimetres (cm).

The Foot Roughness Discrimination Test (FoRDT<sup>™</sup>), described and evaluated previously,<sup>19</sup> 145 assesses haptic tactile sensory ability of the plantar aspect of the foot. It comprises a series of textured 146 147 foot plates, each with standardised and quantifiable gratings. The test involves the haptic exploration of underfoot textured plates in a series of increasingly difficult trials until a roughness discrimination 148 threshold is reached (i.e. the point at which the participant cannot discriminate between two textures). 149 The gratings are expressed as spatial intervals (i.e. the distance between measured in micrometres 150 151  $(\mu m)$  (1 $\mu m = 1/1000$  millimetre (mm)). The larger the spatial interval, the rougher the surface is perceived to be up to a point of between 3000 -3500µm.<sup>25</sup> This provides a roughness discrimination 152 threshold in micrometres (µm). 153

These discrimination tests are undertaken with the participant in standing to reflect, as near as possible, "real life" foot-ground sensorimotor interactions. Upper limb support was provided for safety and to aid participants with balance/weight transfer. Participants were requested to look straight

ahead and avoid looking down at their feet during the testing procedure. In each test, a greaterdiscrimination threshold indicates worse somatosensory ability.

## 159 Measures of balance, gait and falls

160 The *Brief Balance Evaluation Systems Test (Brief BESTest)*<sup>26</sup> is an eight item test, developed 161 from the original BESTest,<sup>27</sup> and assesses six subsystems of static and dynamic balance control: 162 biomechanical constraints, stability limits/verticality, anticipatory postural responses, postural 163 responses, sensory orientation, and stability in gait. Administration time is less than 10 minutes, 164 making it feasible to use in clinical practice, whilst concurrent and convergent validity has been 165 demonstrated in individuals with Parkinson's disease.<sup>28</sup>

166 The 10 metre Walk Test  $(10mWT)^{29}$  was used to assess gait speed (comfortable walking speed

using a rolling start) and stride length calculated in metres per second and steps per metre

168 respectively. The 10mWT is recommended for use in assessing gait speed in PD.<sup>30</sup>

*Falls Incidence*. Falls data was collected through participant retrospective recall over the
 previous three month period. This is recommended as a simple, and effective starting point for
 establishing falls history.<sup>31</sup> We used a well-accepted definition of falls: 'an unexpected event in which
 the participant comes to rest on the ground, floor, or lower level'<sup>32</sup>

Fear of falling. Fear of falling was measured using the *Falls Efficacy Scale - International*(*FES-I*)<sup>33</sup> a 16-item self-report tool, which measures an individual's level of concern about falling
during social and physical activities inside and outside the home. Higher scores indicate greater fear
of falling, which is associated with future falls, activity limitations and reduced quality of life in PD.<sup>34</sup>

177 Statistical analysis

Statistical analyses were performed using SPSS version 22.0. Data were summarised using
frequencies and percentages, mean and standard deviation (SD) or median and inter-quartile range
(IQR) as appropriate. Data distribution was assessed for normality using Shapiro-Wilks tests and
assumed normally distributed when p>0.05. Data presented for the GradDT<sup>TM</sup>, StepDT<sup>TM</sup> and

FoRDT<sup>™</sup> represent discrimination thresholds expressed in the original measurement units. Larger
discrimination thresholds indicate worse sensory function.

Necessary assumptions in reliability testing were accounted for which included stability 184 185 between testing sessions of participant sensory function and consistency in the testing situation 186 (environment, test procedure, medication and time of day). Intra-rater reliability were analysed using Intra class Correlation Coefficient (ICC<sub>2,1</sub>) in line with the Guidelines for Reporting Reliability and 187 Agreement Studies (GRRAS).<sup>35</sup> Standard error of measurement (SEM) provided an indication of the 188 189 score likely due to measurement error. Coefficient of repeatability (CoR), a measure of absolute 190 reliability provided a score change (in the original measurement scale), which included random and measurement error and so any score above CoR reflects true/real change or smallest real difference.<sup>36</sup> 191 It was calculated by multiplying the SEM by 2.77 ( $\sqrt{2} \times 1.96$ ).<sup>36</sup> 192

Sensory performance of the lower limbs of people with PD and matched healthy controls 193 194 allowed for an evaluation of known group validity. A Mann Whitney U test was used to determine 195 statistical significance between the groups (p<0.05) as data for each sensory measures was not normally distributed. Effect size (Cohen's d) was calculated to show the size of any difference, using 196 a standardised formula<sup>37</sup> and interpreted using Cohen's<sup>38</sup> criteria of 0.1 = small effect, 0.3 = medium 197 effect and 0.5 = large effect. Convergent validity was evaluated by comparing our novel tests with the 198 199 EmNSA with the magnitude of the relationship determined using a Spearman's rank order correlation. The magnitude of the relationship between our novel measures of somatosensation and measures of 200 gait, falls and dynamic balance were evaluated using Spearman and Pearson correlational analysis 201 where appropriate. Strength of correlations were interpreted using the classification where  $\leq 0.29 =$ 202 weak, 0.30- 0.49 = moderate and,  $\ge 0.50 = \text{strong.}^{38}$ 203

#### 204 Results

Demographic and clinical characteristics: Fifty-four people, 27 people with PD (mean age 71
 +/- 5.8 years, male/female = 19/8, and 27 age matched healthy adults (mean age 70 +/- 7 years,
 male/female = 17/10) were recruited. Parkinson's participants had a mean Movement Disorder

Society - Unified Parkinson's Disease Rating Scale motor score (MDS-UPDRS III) of 30.11 +/- 14.7
(Table 1)

210 Intra-rater reliability: Test-retest reliability of the novel measures is shown in table 2. Good 211 to excellent mean ICC values were demonstrated in each novel test (ICC =0.72-0.92). Wide 95% 212 confidence intervals in the foot roughness and step height discrimination tests were demonstrated. Coefficient of repeatability scores (i.e. random and measurement error) in the GradDT<sup>™</sup> represented 213 37% of baseline score, 68% in the FoRDT<sup>™</sup> and 55% in the StepDT<sup>™</sup>. Higher scores represent 214 larger random and measurement error. Known Groups Validity: People with PD performed worse on 215 216 sensory measures compared to healthy controls, indicating worse somatosensory function in the lower limbs (Table 3). A Mann Whitney U test revealed significant differences in gradient discrimination 217 thresholds of PD (median= $2.5^{\circ}$ ) and healthy controls (median = $1.4^{\circ}$ , U=179, z=-3.86, p<0.001, 218 r=.52). Foot roughness discrimination thresholds in PD (median  $400\mu m$ ) whilst higher than healthy 219 220 controls (median =300µm) were not significantly different (U=353, z=-1.207, p=0.22, r=0.16). Step 221 height discrimination thresholds were significantly different between PD (median =1.8cm) and healthy controls (median=1.2cm, U=209, z=-3.478, p=0.001, r=0.47). EmNSA tactile sensation scores 222 223 in PD (median =64) were not significantly different from healthy controls (median =62, U=399, Z=-224 0.533, p=0.59, r= 0.07). EmNSA proprioception scores were also not significantly different between people with PD (median =16) and healthy controls (median =16, U=392, z=-1.013, p=0.31, r=0.13). 225 Using the EmNSA sensory measure, 55% of people with PD (n=15/27) scored the maximum 226 score (64/64) on tactile sensation component (range 49-64). In the proprioception component of the 227

229 control performance (88%, n=24/27). In the novel measures, no single person with PD nor control

EmNSA, 81% (n=22/27) of people with PD scored maximally (i.e. 16/16); comparable to healthy

230 participant scored the maximum or minimum.

228

*Convergent validity:* To evaluate convergent validity, strength of associations between the
 novel measures and an existing measure of tactile and proprioceptive sensation, the EmNSA were
 evaluated (table 4). The Foot Roughness discrimination test (FoRDT) showed moderate and
 significant inverse correlation (r=-0.45, p<0.05) with the tactile component of the EmNSA. As tactile</li>

discrimination thresholds increased, scores on the EmNSA fell, indicating worse tactile sensation. No
other significant correlations were demonstrated between our novel measures and the tactile or
proprioception components of the EmNSA (r=0.11-0.28, p>0.05).

238 Associations between novel measures and balance, gait and falls: Gradient discrimination as measured with the GradDT<sup>TM</sup> showed the strongest correlations with functional measures of falls and 239 240 balance (table 5). A significant and strong inverse relationship between the GradDT<sup>TM</sup> and 241 BriefBESTest (r=-0,63, p<0.01) indicates that those with higher gradient discrimination thresholds (i.e worse position sense) had lower scores on the BriefBESTest (i.e worse balance performance). The 242 243 GradDT<sup>™</sup> also showed a strong positive correlation with falls incidence and moderate correlation with the Falls Efficacy Scale – International (FES-I), indicating that those with worse gradient 244 discriminative ability reported more falls (r=0.55, p<0.01) and had greater concerns about falling 245 (r=0.44, p<0.05). No significant associations between any sensory measure and spatial or temporal 246 247 aspects of gait were demonstrated.

#### 248 Discussion

249 In this study, we evaluated three novel tests of lower limb somatosensory function in a cohort of people with PD and healthy age matched control participants. The sensory-perceptual ability to 250 251 discriminate surface gradient or slope was assessed during full weight-bearing using the GradDT<sup>TM</sup>. 252 Discrimination of step height using lower limb position sense was assessed with the StepDT<sup>TM</sup>, and the ability to discriminate underfoot surface roughness was evaluated using the FoRDT<sup>TM</sup>. Our study 253 results provide preliminary evidence to support the reliability and validity of these tests in people with 254 255 PD, and demonstrate people with PD to have impaired lower limb somatosensory discrimination. 256 Moreover, these deficits are associated with worse static and dynamic balance, greater falls incidence 257 and fear of falling.

Our novel measures target key sensorimotor functions related to stance and stepping and use a robust psychophysical testing approach to establish somatosensory discrimination thresholds, i.e. the ability to discriminate the spatial qualities (roughness/gradient/step height) of a stimulus. In contrast 261 to the more traditional, manual method of assessing lower limb movement detection and direction (i.e. the proprioceptive component of the EmNSA), our weight-bearing tests of gradient discrimination 262 (GradDT<sup>TM</sup>) and step height discrimination (StepDT<sup>TM</sup>) highlighted increased somatosensory 263 discrimination thresholds in people with PD and found these deficits had moderate to strong 264 265 significant correlations with balance, reported falls and concern about falling. In line with our findings, elevated somatosensory discrimination thresholds to temporal stimuli (STDT), that is, the 266 267 shortest time interval required for two tactile stimuli to be perceived as separate, have also been found 268 in people with PD compared to healthy controls. Elevated discrimination thresholds at the finger and face<sup>39</sup> and toe<sup>40</sup> have been identified in PD, and have mostly been observed to be correlated with 269 movement performance<sup>41</sup>; our findings lend further support to the presence of somatosensory 270 dysfunction in people with PD, and its impact on movement performance, movement function and 271 272 sensorimotor integration.

273 Movement and balance are reliant on a complex interaction between sensory and motor systems<sup>42</sup> whilst the central processing of sensory information ensures the production of a motor plan 274 for task execution that is appropriate to the sensory environment.<sup>43</sup> In PD it is postulated that deficits 275 of central processing of somatosensory information, rather than pathology of the peripheral nervous 276 277 system result in altered integration of sensory and motor information<sup>4,44</sup> and in particular proprioceptive information<sup>45</sup>. An important function of the dorsal striatum within the basal ganglia 278 (one of the main channels of information processing) is suggested to be the treatment of sensory and 279 280 motor information coming from the sensorimotor cortex and integrating visual and proprioceptive information onto the motor command.<sup>46</sup> Using methods which target the integrity of these central 281 282 processes and the perceptual constructs they sustain may be better achieved by sensory measures 283 which assess discriminative perception rather than simple touch or movement detection. Our data 284 suggest our lower limb novel measures may be better suited to capturing the complexity of 285 somatosensory dysfunction in PD compared to an existing, widely used clinical measure.

That our novel measures of gradient discrimination and step height discrimination were only
weakly correlated with the proprioceptive component of the EmNSA suggests they may be measuring

different constructs. This may, at least in part, be accounted for by the fact that the EmNSA assessed proprioception with the participant in supine/sitting, in contrast to our novel measures which assessed position sense with the participant standing in full weight-bearing. Sense of position and sense of movement have also been shown by others to only weakly correlate<sup>47</sup> which may further help to explain this finding.

293 The presence of plantar tactile sensory dysfunction in people with PD was not evident in this 294 study as neither tactile scores of the EmNSA nor discrimination thresholds to roughness perception 295 (FoRDT<sup>TM</sup>) were significantly different from healthy controls. Furthermore, tactile plantar sensation 296 as measured by the FoRDT<sup>™</sup> did not significantly correlate with our mobility outcomes. Current 297 evidence pertaining to the presence of plantar tactile sensory deficits in people with PD is equivocal<sup>4,48</sup> with contrasting results explained by variations in study sample characteristics such as 298 disease stage, symptom severity and sensory assessment methods. That most participants in our study 299 300 were in the early-moderate stages of PD (mean Hoehn & Yahr stage =2.3; time since diagnosis =5.7 years) suggests that reported plantar tactile sensory changes may not occur in early PD. We also 301 recognise the complex and multifactorial nature of balance impairment in PD and the involvement of 302 several 'systems' in addition to the somatosensory system<sup>27</sup> and so factors other than plantar tactile 303 304 deficits may also contribute to balance deficits. Nonetheless, that significant deficits of plantar 305 sensation were not evident in our sample, yet proprioceptive deficits were, supports the potential for 306 interventions targeting the plantar aspect of the foot to enhance lower limb position

307 sense/proprioception.

Our study supports that diminished position sense awareness of the lower limbs may also contribute to an increased risk of falls. The strong and significant correlations between lower limb position sense as measured with the GradDT<sup>TM</sup> and StepDT<sup>TM</sup> falls incidence and falls confidence indicates worse position sense awareness of the lower limb is significantly associated with more falls and greater fear of falling. This is in line with the findings of others who have found greater error performance and variability in judging obstacle heights when relying on lower limb proprioception<sup>10</sup> which may contribute to an increased risk of trips; and that people with PD who fall have significantly

worse lower limb proprioception, compared to those who don't fall.<sup>7</sup> The link between falls and lower
limb proprioceptive impairment has also been identified in other clinical populations.<sup>16,49</sup>

317 Neither temporal nor spatial aspects of gait, as measured by straight line gait speed and 318 number of steps, respectively, were significantly associated with lower limb somatosensory function. 319 Similar findings have been identified in previous studies of healthy and neurological populations<sup>16,50</sup> 320 and explained by the increased use or sensory weighting of visual information during walking tasks, 321 which may reduce the need for accurate somatosensory information from the lower limbs. In essence, 322 'simple' straight line gait tasks may be completed using minimal somatosensory information and 323 processing as visual feedback compensates. EEG studies, <sup>51,52</sup> demonstrate that more complex gait tasks, such as uphill walking and narrow beam walking result in increased activation within 324 somatosensory cortical regions compared with simple straight line gait tasks on the flat, suggesting a 325 greater role for somatosensory information during more complex walking tasks. 326

327 Intra-rater reliability was excellent in the GradDT<sup>TM</sup> although wide reliability confidence intervals and substantial coefficient of repeatability scores for the FoRDT<sup>TM</sup> and StepDT<sup>TM</sup> highlight 328 329 the occurrence of random and/or measurement error. Reliability is an issue in sensory assessments particularly in neurological populations<sup>12</sup> and whilst we attempted to control for random and 330 measurement error, we postulate that the effect of fluctuations in participant energy levels, fatigue and 331 332 possibly attention, may account for this. The clinical implication is that somatosensory function in people with PD, as with other symptoms, may not be established through one-off assessments, but 333 should be assessed on several occasions in order to gain a true picture. Nonetheless, our novel 334 335 measures have demonstrated to have distinct advantages over existing measures of lower limb 336 sensation in that they employ an interval level of measurement and show, in this sample, no floor or 337 ceiling effects. The SEM and CoR data provide an indication of random and measurement error which enables interpretation of the true change in scores. Because the CoR is quantified in the same units as 338 339 the assessment tool, it lends itself for easy clinical interpretation, and can be used to guide decision making. A change in discriminative ability in the gradient test of +/- 0.85° for example, would 340

indicate change beyond random and measurement error; critical for the monitoring of diseaseprogression and the evaluation of interventions.

343 This study has several limitations. The testing of discriminative ability places demands on 344 cognitive functions such as attention and working memory; functions which are known to be affected in PD<sup>53</sup> and may be further confounded by fatigue and/or motivation.<sup>54</sup> Formal assessment of fatigue 345 346 or motivation was not undertaken in this study, so the extent to which it influenced test outcome 347 cannot be determined. We also did not run separate analysis on the effect of lower limb tremor or dyskinesia on somatosensory performance so cannot rule out the impact of these symptoms as our 348 349 novel tests were designed to reflect 'real life' foot-ground sensorimotor interactions during weightbearing. A further limitation relates to the generalisability of our findings. Our sample was comprised 350 351 of people in the mild to moderate stages of PD who were tested during the 'ON' phase, and so the results may not generalise to those in the more advanced stages of the disease, nor reflect 352 353 somatosensory function during the 'OFF' phase.

### 354 Conclusion

355 To develop targeted and appropriate rehabilitation interventions for people with PD, the recognition that lower limb sensation informs movement and balance function is critical. Key to this 356 357 is the availability and use of appropriate, clinically feasible and psychometrically robust assessment 358 tools. The development and use of sensory measures which are more closely aligned with the complex 359 sensory-motor function of the lower limb, such as the novel measures evaluated in this article, may enhance understanding in this relatively understudied area of PD. It is hoped that this study provides 360 361 further insight, and generates discussion into recognising the importance of evaluating somatosensory 362 ability, its relevance to movement, and its rehabilitation in this clinical population.

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#### 367 Author Roles

- 368 1. Research project: A. Conception, B. Organization, C. Execution;
- 369 2. Statistical Analysis: A. Design, B. Execution, C. Review and Critique;
- 370 3. Manuscript Preparation: A. Writing of the first draft, B. Review and Critique
- **T.G.:** 1A, 1B, 1C, 2A, 2B, 2C, 3A, 3B
- **J.F.:** 1A, 2C, 3B
- 373 **J.M**.: 2A, 3B
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- 380 University of Plymouth, Faculty of Health and Human Sciences Research Ethics Committee (ref:
- 381 17/18-86). Written informed consent was gained from each participant prior to taking part in this

382 study and documented. We confirm that we have read the Journal's position on issues involved in

383 ethical publication and affirm that this work is consistent with those guidelines.

384

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	PD	Control
Characteristics	(n=27)	(n=27)
Age, years, mean (SD)	71 (5.8)	70 (7.0)
Gender n (%)		
Male	19 (70.4)	17 (62.9)
Female	8 (29.6)	10 (37.1)
<b>Fime since diagnosis, years mean</b>		
SD)	5.7 (4.9)	-
Ioehn & Yahr stage, n (%)		
	3 (11.1)	-
2	14 (51.9)	-
•	9 (33.3)	-
	1 (3.7)	-
ADS-UPDRS Score, mean (SD)	30.1 (14.7)	
Number of falls reported n (%)		
)	12 (44.4)	20 (74)
l	3 (11.1)	4 (15)
2	2 (7.4)	3 (11)
3	4 (14.8)	0
>4	6 (22.3)	0

 Table 1. PD and control participant demographic and clinical characteristics

# 541 Table 2. Intra-rater reliability of novel sensory measures

	Intra-rater Reliability (Parkinson's $n=27$ )					
Measure	Test 1 (T1)	Test 2 (T2)	Mean (T1 &T2)	SEM	ICC <sub>(2,1)</sub> (95% CI)	CoR
GradDT <sup>™</sup> threshold degrees (°) mean (SD)	2.4 (1.2 )	2.2 (1.0)	2.3 (1.1)	0.31	0.92 (0.82-0.96)*	0.85
FoRDT™ threshold µm, mean (SD)	480 (240)	520 (210)	500 (235)	124	0.72 (0.38-0.87)*	340
StepDT™ threshold cm mean (SD)	1.8 (0.9)	1.9 (0.7)	1.8 (0.7)	0.36	0.73 (0.40-0.88)*	1.0

Abbreviations: GradDT, Gradient Discrimination Test; StepDT, Step-height Discrimination Test; FoRDT, Foot Roughness Discrimination Test; cm, centimetres; SD, Standard Deviation; SEM, Standard error of measurement; ICC(2,1) Intraclass Correlation Coefficient model 2,1; CI, Confidence Interval; CoR, Coefficient of Repeatability \*P<0.001

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# Table 3. Comparison of sensory performance between people with Parkinson's disease (PD) and

# 559 healthy control group

Sensory Measure	PD (n=27)	Control (N=27)	р	Effect Size d
GradDT <sup>TM</sup> threshold degrees (°) Median (IQR, range)	2.5° (1.75°, 5.5°)	1.4° (1.1°, 2.5°)	<0.001	0.52
FoRDT™ threshold µm Median (IQR, range)	400 (400, 900)	300 (325, 850)	0.22	0.16
StepDT <sup>™</sup> threshold cm Median (IQR, range)	1.8 (1.2, 3.0)	1.2 (0.6, 1.8)	0.001	0.47
EmNSA score, median (IQR, range Tactile Sensation (0-64) Proprioception score (0-16)	64 (7,15) 16 (0, 2)	62 (4,13) 16 (0,2)	0.59 0.31	0.07 0.13

Abbreviations: GradDT, Gradient Discrimination Test; StepDT, Step-height Discrimination Test; FoRDT, Foot Roughness Discrimination Test; EmNSA, Erasmus modified version of Nottingham Sensory Assessment; cm, centimetres; SD, Standard Deviation;  $\mu$ m, micrometres; *d* Cohen's *d*.

574 Table 4. Spearman rank order correlation coefficients between novel measures and Erasmus MC

575 modified Nottingham Sensory Assessment

	EmNSA Sensory Modality			
Sensory Measure	Tactile Score	Proprioception Score		
GradDT™	-0.25	-0.21		
StepDT <sup>TM</sup>	-0.29	-0.28		
FoRDT <sup>TM</sup>	-0.45*	-0.11		

\*p<0.05

Åbbreviations: EmNSA, Erasmus MC modified Nottingham Sensory Assessment; GradDT<sup>™</sup>, Gradient Discrimination Test; StepDT<sup>™</sup>, Step Height Discrimination Test; FoRDT<sup>™</sup>, Foot Roughness Discrimination Test

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592 Table 5. Spearman rank order correlation coefficients between sensory measures and functional593 mobility measures

	Falls Incidence	Falls Efficacy Scale -I	Brief BESTest	Gait Speed m/s	Step length
Sensory Measure					
GradDT	0.55**	0.44*	- 0.63**	0.20	0.06
StepDT	0.24	0.1	- 0.54**	0.12	0.09
FoRDT	0.03	0.15	-0.11	-0.17	0.05
EmNSA (Tactile)	-0.21	-0.37	0.17	0.03	0.02
EmNSA (Proprioception)	0.15	-0.37	-0.31	0.15	0.17

\*p<0.05; \*\*P,0.01; Abbreviations: GradDT, Gradient Discrimnation Test; StepDT, Step height discrimination test; FoRDT, foot roughness discrimination test; EmNSA, Erasmus MC modified Nottingham Sensory Assessment; FES-I, Falls Efficacy Scale – International; BriefBESTest, Brief version of Balance Evaluations Systems Test;

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