

# A framework to standardize gait study protocols in Parkinson's disease

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## 1 BACKGROUND

- Gait impairments strongly influence quality of life in PD.
- Currently, clinical trials in PD are limited by the low sensitivity of gold-standard, outcome measures that are subjective, and usually consist of qualitative clinical rating scales that require expertise.
- Research from the past twenty years on gait has shown a high sensitivity for diagnosis, even in early disease, and the ability to capture the effects of interventions and monitor disease progression.
- Nonetheless, the lack of standardization in protocols and reported gait measures is impeding data aggregation across centers and contributes to heterogeneity in the results, thus limiting the adoption of gait outcomes in clinical trials.

### OBJECTIVE

*To provide recommendations for a minimum set of gait outcome measures to be adopted in projects evaluating people with Parkinson's disease (PD).*

## 2 METHODS





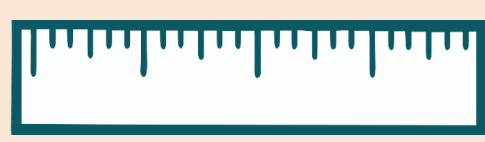
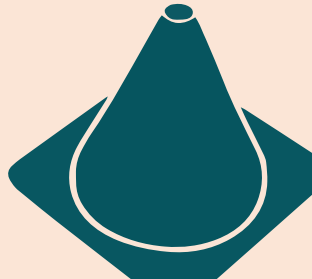

- The GALOP committee is an advisory committee for the Michael J Fox Foundation for Parkinson's research. The committee comprises a person with PD living with gait issues and experts in the field of gait, from academia and clinical care, who aim to progress research and treatment of gait impairments.
- GALOP is leading the effort in generating a set of recommendations for the standardization of protocols assessing quantitative gait measures following best practice to be used as consensus guidelines in prospective gait studies.

## 3 RESULTS

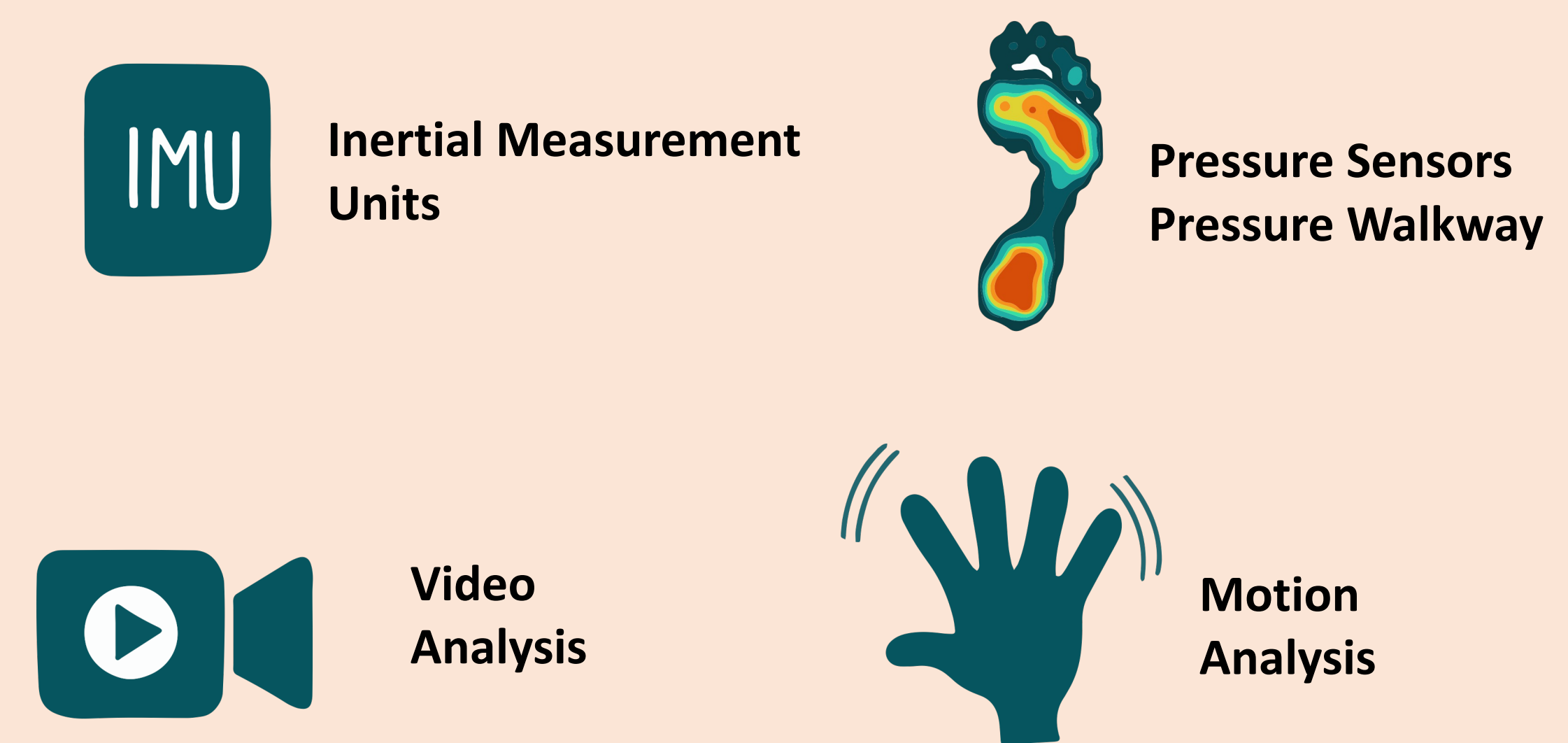
### Recommended minimum set of meta-data to accompany gait protocols

| Demographics   | Clinical   |
|--|--|
| <ul style="list-style-type: none"> <li>• Age</li> <li>• Sex at birth</li> <li>• Height and Weight</li> <li>• Education (in years)</li> <li>• Disease duration (in years from diagnosis)</li> </ul> | <ul style="list-style-type: none"> <li>• Montreal Cognitive Assessment (MoCA)</li> <li>• MDS-UPDRS (ALL parts separately and total)</li> <li>• Hoehn and Yahr stage</li> <li>• Presence of tremor since diagnosis (Yes / No)</li> <li>• PD-related Pharmacological Therapy: Levodopa Equivalent Daily Dose (LEDD)</li> <li>• Presence of Deep Brain Stimulator (Yes / No)</li> <li>• Presence of Infusion pump (Yes/No)</li> <li>• Presence of FOG (Yes/No)</li> <li>• Falls (number of falls in the past six months)</li> </ul> |

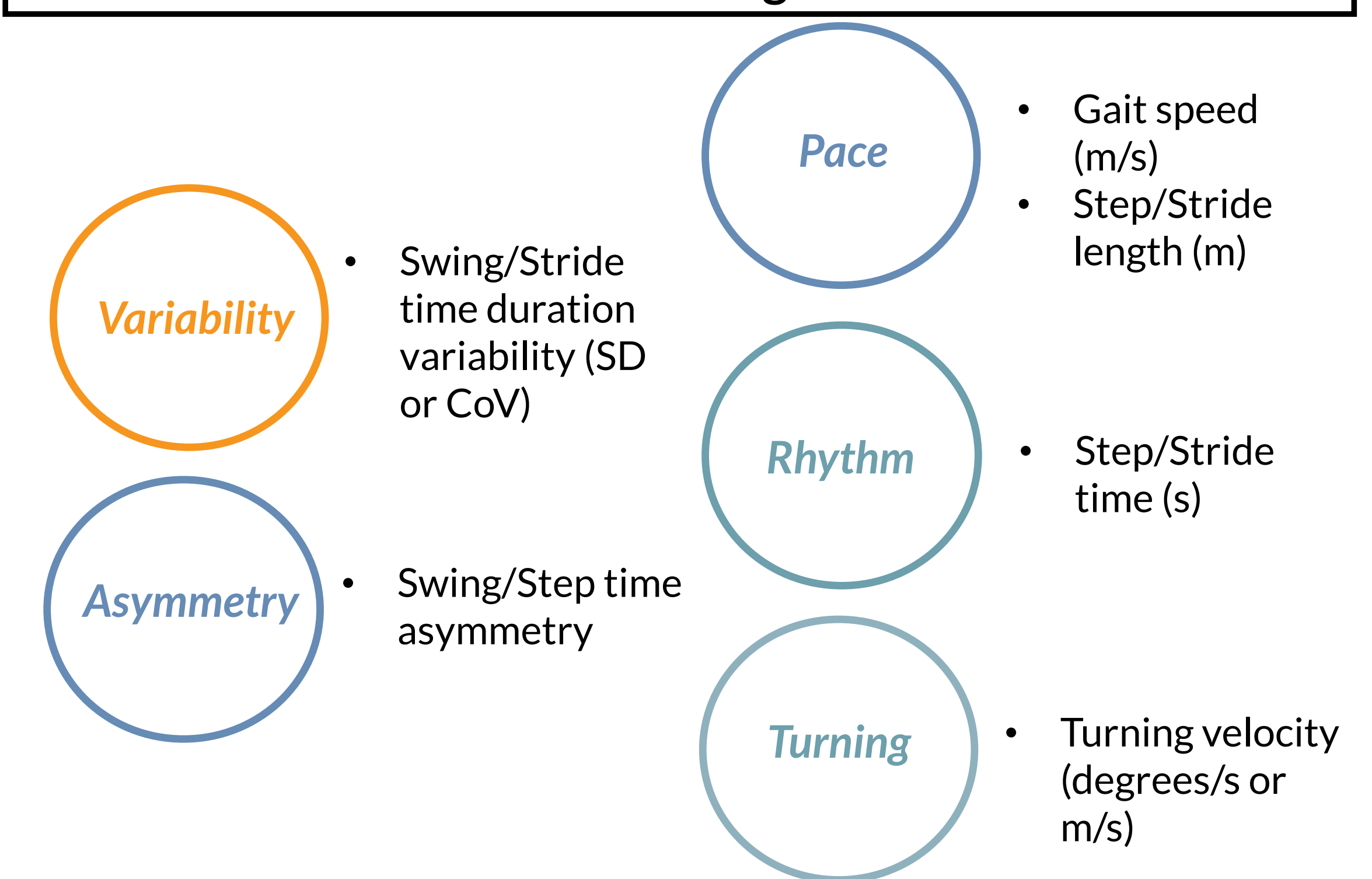
### Recommended Gait protocol and technology

|  |   |
|--|---|
| <b>Medication Status:</b><br>ON / OFF<br> | <b>Supervised/Unsupervised Data Collection</b><br>In-home  In-clinic  |
|  <b>Walk Speed</b><br>Walk Duration       |  <b>Walkway Length (m)</b>   |
| <b>Turning Strategy</b><br> Around a cone |  180° turn   |

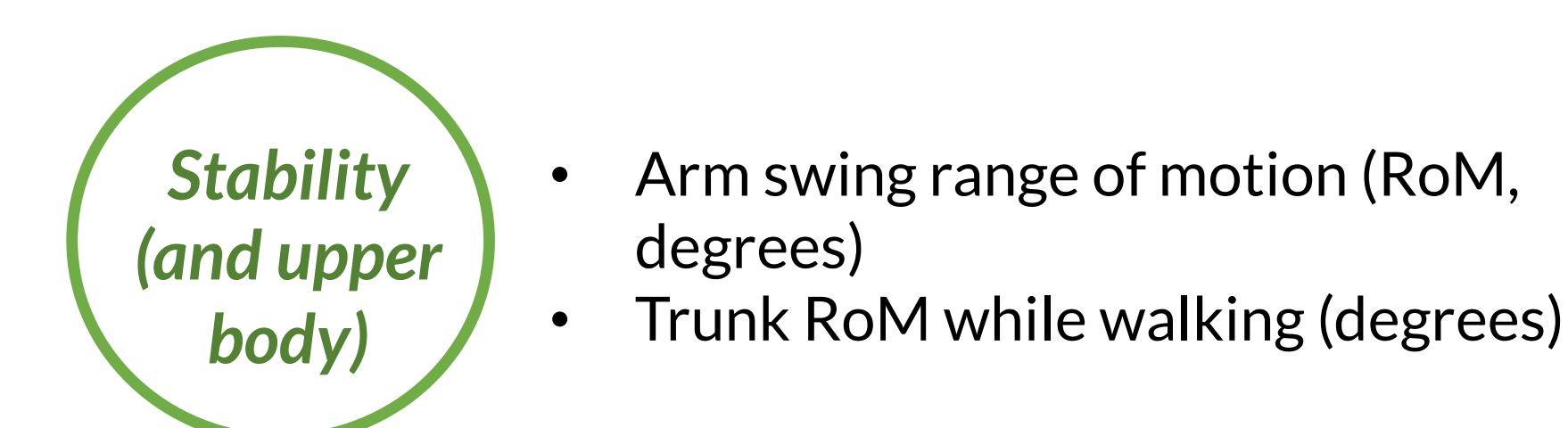
**Technology:** studies should use at least one of the following and record specific information regarding hardware and software used during all measured observations. Raw data should be made available.



### Recommended minimum set of gait outcome measures

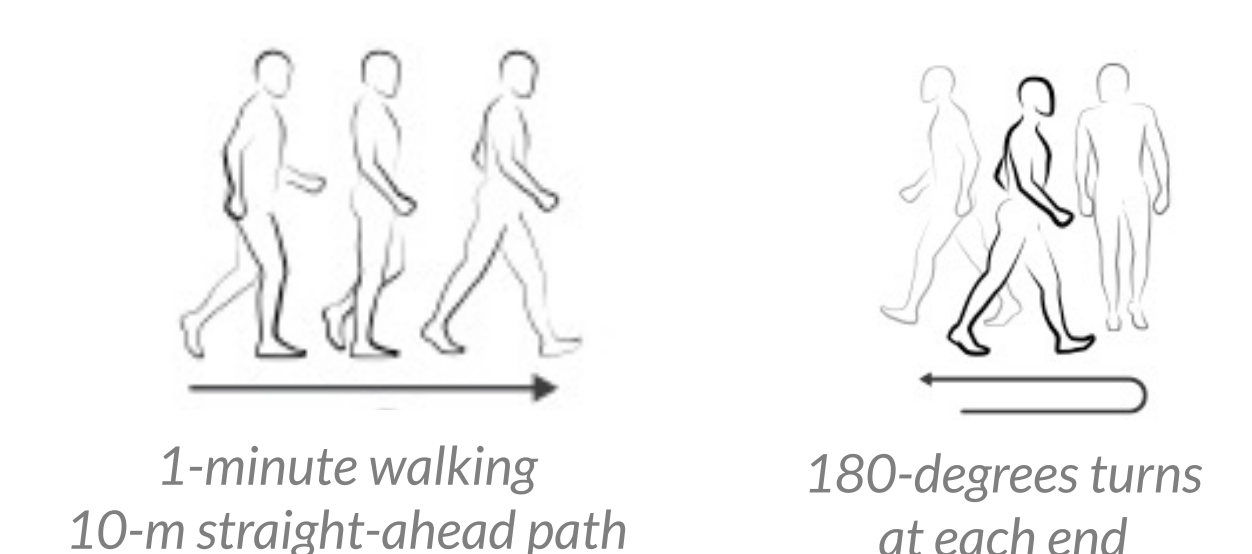


### If available



### Additional recommended considerations

- A straight-line path of 10 m (+1 m at each end to accommodate safe turning) for at least 1-minute of walking at a comfortable speed (minimally) with 180-degree turn is recommended.



- If adding a concurrent dual-task condition, we recommend one of the following options:
  - Arithmetic: N-back
  - Memory: Digit Span Forward
  - Language: Letter Fluency

## 4 DISCUSSION

- This work will be integrated into research programs addressing gait impairment selected for funding by MJFF.
- Our objective is to support the scientific community by generating recommendations to collect and share gait data gathered from people with PD using an open data repository.
- Our long-term goal of standardizing gait protocols and outcomes in PD has the potential of accelerating research and clinical trial results, harmonizing protocols across centers and fostering collaborations.

## REFERENCES

1. For previous literature of dual-task conditions, see Raffegau T. et al., PRD 2019, Kelly V. et al., PRD 2012.
2. Gait measure recommendations are partly consistent with the NINDS Best Practice for Digital Health Outcomes in PD. [https://www.commondataelements.ninds.nih.gov/sites/ninds/files/Doc/PD/F3012\\_Best\\_Practices\\_for\\_Digital\\_Health\\_Outcomes.pdf](https://www.commondataelements.ninds.nih.gov/sites/ninds/files/Doc/PD/F3012_Best_Practices_for_Digital_Health_Outcomes.pdf)

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