Report of Research Results

(A) Title: You can't fix what you can't see – improving assessment methods for freezing of gait in people with Parkinson's disease

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(C) Summary: Include the outline and conclusions of the research

Freezing of gait is common in people with Parkinson's, and can be distressing and disabling. Freezing of gait can be triggered by narrow spaces, change in walking direction, and anxiety. Assessment of freezing of gait can be difficult in the clinical setting due to its episodic nature, and can be easily missed by clinicians. Accurate assessment of gait freezing is important so that targeted treatment can be given to minimize disability. Although a specific self-reported outcome measure (Freezing of Gait Questionnaire) has been recommended for clinical use, there are no suitable objective measures. This research aimed to validate a newly-developed clinician-rated tool for clinical evaluations of freezing of gait severity in people with Parkinson's disease

This cross-sectional study investigated the validity, responsiveness, and reliability of the developed tool. We have recruited 41 out of the targeted 100 people with Parkinson's disease. The validity, responsiveness, and reliability were evaluated through two assessment sessions, conducted in a single day. Preliminary analyses of results found adequate construct validity and excellent test-retest reliability, but responsiveness remains to be determined. Further research with more definitive markers for change, such as assessing before and after an intervention known to be effective, is required to establish the responsiveness of the newly-developed tool.

(D) Aim of Research

To investigate the validity, reliability, and responsiveness of a newly developed tool in a sample of people with Parkinson's disease living in Singapore.

(E) Method of Research & Progression

Validity, reliability, and responsiveness of clinician-rated tool

The target recruitment was one hundred people with idiopathic Parkinson's disease. Forty-one people with Parkinson's were screened and recruited from neurology and physiotherapy clinics at the Singapore General Hospital. They were evaluated using a newly-developed clinician-rated tool based on expert consensus from a Delphi study and were asked to perform a series of functional tasks, including walking with a turn and sitting-to-standing tasks. Questionnaires examining anxiety (i.e., Parkinson Anxiety Scale), cognitive ability (i.e., Montreal Cognitive Assessment), and self-perceived freezing of gait severity (i.e., Freezing of Gait Questionnaire) were also administered. Participants were assessed twice with the clinician-rated tool and functional tasks – first, before the questionnaires; second, after the questionnaires. Construct validity of the newly-developed clinician-rated tool was explored through correlations with similar constructs, dissimilar but related constructs, and unrelated constructs. Reliability was examined by comparing the scores of both assessments in people who reported no difference in medication state, using intraclass correlation coefficient. Responsiveness was planned to be estimated by calculating the minimal clinically important difference, using results of participants who reported being "slightly better" in the post-questionnaire assessment.

We started recruitment in August 2021 from the physiotherapy clinics at the Singapore

General Hospital due to a delay in the signing of a research collaboration agreement with our overseas collaborators. Additionally, we had difficulty in hiring a part-time associate research coordinator. We finally managed to hire a staff who started work on 18 October 2021. To improve recruitment, we started screening and recruiting patients at the Neurology clinics in October 2021.

Reliability of clinician-rated tool
Reliability of the newly-developed clinician-rated tool was originally intended to be based on the scores of two assessment sessions conducted on two separate days, spaced no more than two weeks apart. Due to COVID-19 restrictions on research and clinic appointment availability, no participants were able to return for a second assessment session on a separate day. Thus, test-retest reliability was estimated with scores from two sessions conducted on the same day instead.

(F) Results of Research

41 participants have been recruited and completed the assessments on the initial visits. Preliminary analyses, based on the first 39 participants, showed that the newly-developed clinician-rated tool had sufficient criterion-related validity – with good correlation with existing assessments of freezing of gait severity (Freezing of Gait Questionnaire, Rho = 0.73, 95% CI 0.54 – 0.85, $p < 0.001$). Construct validity was adequate, with moderate correlation with assessments of disability (Unified Parkinson's Disease Rating Scale: Part II, Rho = 0.57, 95% CI 0.30 – 0.75, $p < 0.001$; Part III, Rho = 0.59, 95% CI 0.31 – 0.77, $p < 0.001$), and no significant association with unrelated constructs of cognition (Montreal Cognitive Assessment, Rho = -0.14, 95% CI -0.46 – 0.19) and anxiety (Parkinson Anxiety Scale, Rho = 0.17, 95% CI -0.17 – 0.49). Test-retest reliability was excellent in fifteen participants who reported the same medication state (ICC = 0.96, 95% CI 0.86 – 0.99, $p < 0.001$). For responsiveness, minimal clinically important difference could not be calculated as too few participants reported being "slightly better" in the post-questionnaire assessment. Thus far, there have been no complaints on the study, and no adverse events reported.

(G) Future Areas to Take Note of, and Going Forward

From our experience with the 41 patients recruited thus far, we have noticed anecdotally that freezing of gait have been missed by the primary clinicians during standard clinical assessment as the current tests failed to trigger freezing episodes in the clinical setting. Only five of the recruited participants experienced a freezing episode in the standard clinical assessments. In contrast, freezing of gait was observed in 31 participants during the newly-developed clinician-rated tool's assessment.

To determine the responsiveness of this newly-developed tool, more definitive markers of change may be required. Further research with more purposeful change, such as assessing before and after an intervention known to be effective, may help establish the responsiveness of this newly-developed tool.

(H) Means of Official Announcement of Research Results

Recruitment has paused as the study team has been invited to an international meeting to harmonize freezing of gait research worldwide. Following the meeting, the research protocol will be reviewed as required. We have presented the preliminary results of this study at local conferences (Singapore Allied Health Conference and SGH 23rd Annual Scientific Meeting 2022). A journal article has been drafted and submitted to a peer-reviewed journal (currently Movement Disorders Clinical Practice) for consideration for publication. This was previously submitted to Parkinsonism and Related Disorders journal, but the journal's recommendation was to transfer the manuscript to an open access journal which required a publication fee.