Charco Neurotech
CUE1 User Testing Report

Using MDS-UPDRS Part III as the primary outcome, the results indicated a positive response across **91.6%** of all participants, with a mean improvement of **8.34** points.

Report date: December 2022

Introduction

CUE1
FOR PARKINSON'S

A non-invasive, wearable, medical device for people with Parkinson's, to improve movement and quality of life.

Charco Neurotech developed a medical device utilising high frequency vibrotactile stimulation combined with cueing to improve motor outcomes in people with Parkinson's disease. It is the first device combining the two therapies to be granted regulatory approval in the UK and EU for this purpose. This study represents real world data (RWD) from volunteers who live with Parkinson's disease using the device. Data captured included a mixture of quantitative and qualitative assessments as well as a Patient Reported Outcomes (PRO). The primary outcome measure is the MDS-UPDRS Part III motor score, the gold standard.

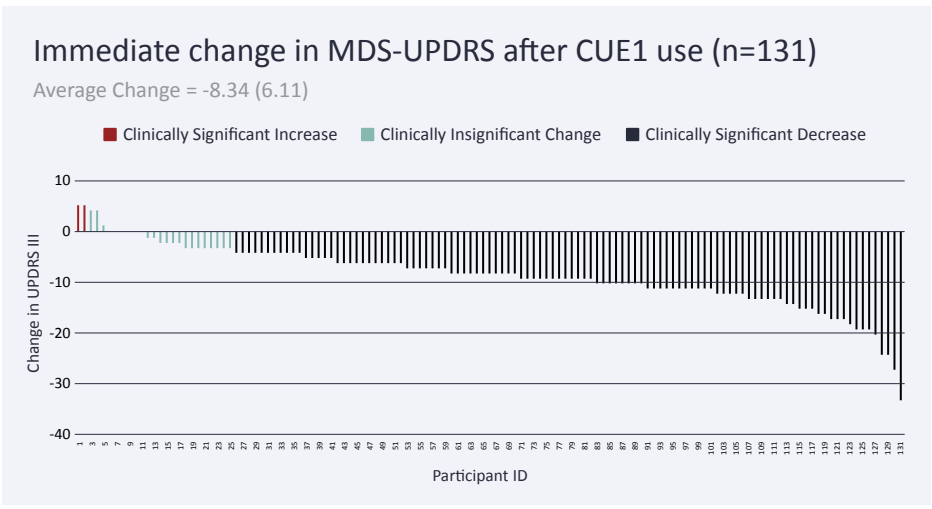
Methods

131 participants with idiopathic Parkinson's disease volunteered for this study. Participants were between stage 1 and 4 on the Hoehn & Yahr Scale.
All participants were examined and tested using the **MDS-UPDRS Part III** motor score, and a proportion completed the Timed Up and Go **(TuG)** test for immediate effectiveness. The Parkinson's Impact Scale **(PIMS)**, a quality of life questionnaire, the Scales for Outcomes in Parkinson's Disease **(SCOPA)**, and further feedback questionnaire to investigate usability, tolerability, and risk profile were performed at baseline and at least two weeks of home use to assess the impact of Parkinson's on the participant's lives and their subjective symptom severity.
The TuG test involves timing a participant starting in a seated position, rising from the chair, walking 3 metres, turning, and walking back to the chair.
The timer is stopped once they have returned to their seated position. The examiners were non-blinded.

Results

MDS-UPDRS Overall

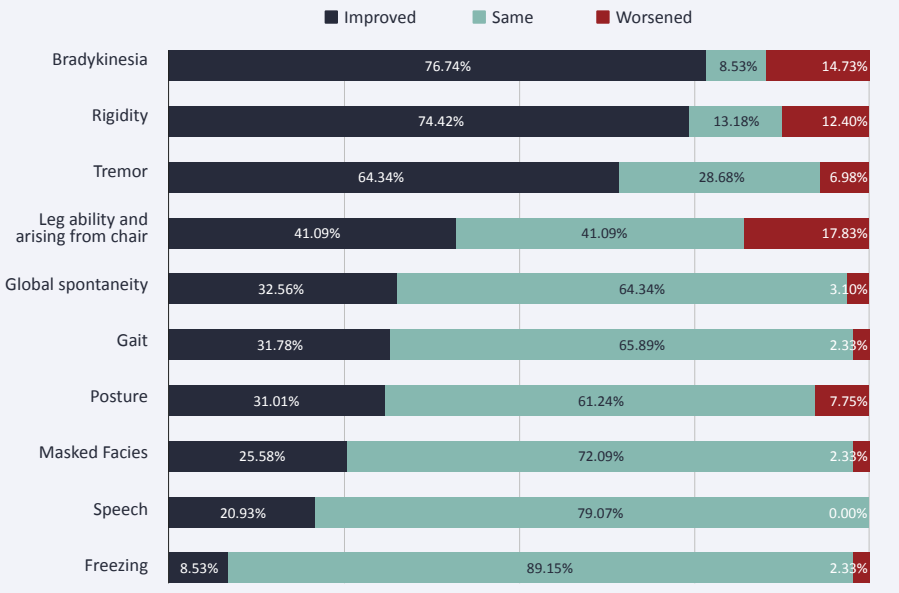
The Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS Part III motor score) is a widely used clinical research method to evaluate the disease progression and severity for individuals with Parkinson's by assessing its symptoms. Therefore, the more severe symptoms an individual has, the higher MDS-UPDRS score they will have. This graph presents the improvement in symptoms that people show immediately after turning on the CUE1. From a sample of 131 people with ranging severities, 120 people (92%) improved. From these, 106 (81%) showed a clinically significant improvement. Improvements are considered clinically significant when more than the quoted Minimal Clinically Important Difference (MCID) of -3.25[(1)]. Finally, the average improvement observed by using the CUE1 device was -8.34 points, around 5 more than the MCID.



[1]Horváth, K., Aschermann, Z., Ács, P., Deli, G., Janszky, J., Komoly, S., & Kovács, N. (2015). Minimal clinically important difference on the Motor Examination part of MDS-UPDRS. Parkinsonism & related disorders, 21(12), 1421-1426.

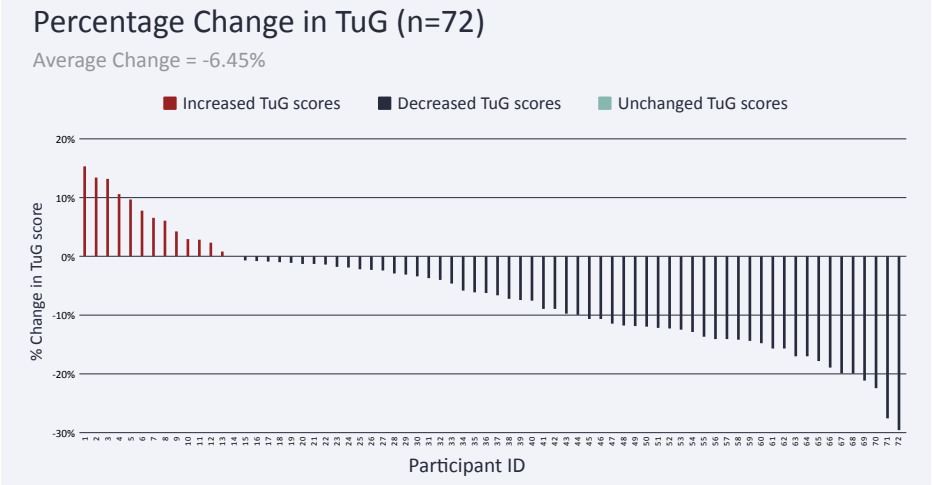
Symptoms

Taking a closer look at the MDS-UPDRS subsections, the results showed **overall improvement** across each domain. The most common improvements were seen in **bradykinesia, rigidity and tremor.** This reflects the current specific literature describing effectiveness of vibrotactile stimulation in Parkinson's disease. Unexpected results included moderate improvement in speech and masked facies, which can be particularly debilitating symptoms and are traditionally more difficult to treat.
There were some improvements in gait and posture, however the majority showed no change from baseline.



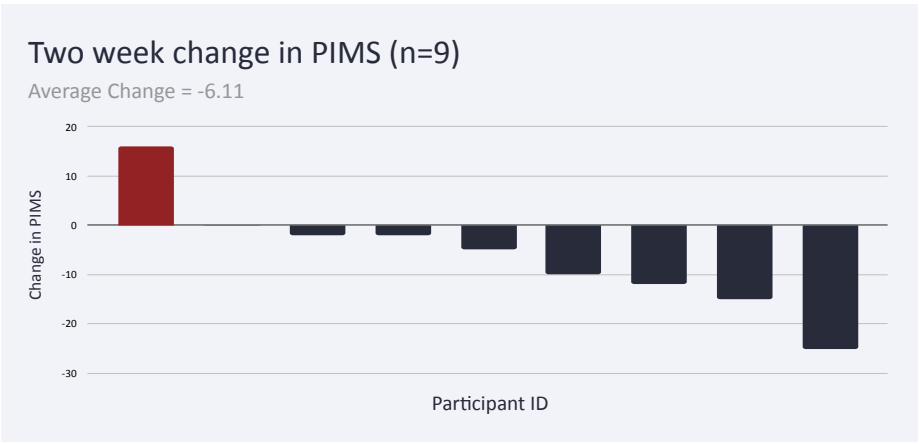
Timed Up and Go (TuG)

72 participants completed the TuG test at the initial assessment. All participants completed the TuG test at baseline and immediately after wearing the CUE1. The average TuG score at baseline was 13.7 seconds. 58 participants (81%) showed improvement in TuG scores. The average percentage improvement across all participants was **6.45%.** Participants also reported feeling their movement was smoother and better coordinated.



Parkinson's Impact Scale (PIMS)

9 participants completed the PIMS, which assesses the **impact of idiopathic Parkinson's disease on aspects of the participant's emotional, social and economic life.** Participants completed PIMS at least twice, once before the use of the CUE1, and once after using the CUE1 for at least 2 weeks. The average change in score was -6.11, with the maximum change being an improvement by 25 points. 1 of the 8 participants demonstrated a worsening of impact by 16 points.



Scales for Outcomes in Parkinson's Disease (SCOPA)

9 participants completed the SCOPA, which assesses various symptoms experienced by patients with idiopathic Parkinson's disease including **cognitive dysfunction, psychosocial functioning and motor function.** Participants completed the SCOPA twice, once before the use of the CUE1, and once after using it for at least 2 weeks. The average improvement was 1.22, with the maximum change being an improvement by 4 points, and the minimum being an improvement of 1 point. 3 of the 9 participants reported worsening of symptoms, but these changes were comparatively small and one returned to baseline at 4 weeks.

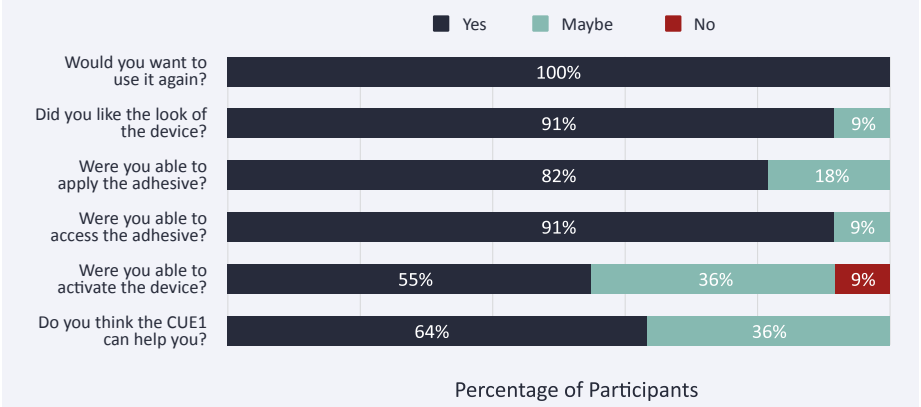
Two week change in SCOPA (n=9)

Average Change = -1.22

Patient ID	Baseline SCOPA	Two week SCOPA	Change in SCOPA
1	0	2	2
2	8	9	1
3	13	14	1
4	9	8	-1
5	8	6	-2
6	6	4	-2
7	7	5	-2
8	15	11	-4
9	8	4	-4

Feedback Questionnaire

11 participants completed the feedback questionnaire. Efficacy results demonstrated that 100% of participants believed the device 'can' or 'maybe' able to help. Those that said 'maybe' said that they would like to use the device longer to be more definite. **100% of participants said they would use it again.** For usability, 55% of participants were able to activate the device fully and 36% to some extent. 9% completely failed to activate the device. This resulted in a key simplification in the activation process from a triple-click to a single-click of the button. 100% of the participants said that the device **did not cause any pain, discomfort, intrusion or noise.**



Discussion

These results demonstrate the **positive effects of the CUE1** as measured by movement assessments, tasks and questionnaires in a non-randomised, open-label non-clinical study. 91.6% of all participants showed improvement, although to varying degrees. The mean MDS-UPDRS Part III motor score improvement was 8.34 points at immediate assessment. The MDS-UPDRS subsections showed that such improvements were most marked in **bradykinesia, rigidity and tremor.** Perhaps such improvements in fine and gross motor skills are responsible for improvements in speech, facial motor symptoms and the TuG assessments. PIMS and SCOPA showed that the impact of Parkinson's disease symptoms and their severity has lessened, and the positive impact was reflected in **100% of the participants** being willing to use the CUE1 in the future.

Conclusion

The CUE1 is a novel non-invasive medical device which presents a new arm in the line of therapies available to help manage Parkinson's disease. **An average improvement of 8.34** (s.d. 6.11) points above baseline was seen in the MDS-UPDRS Part III motor scores with the CUE1 intervention, which is significantly higher than a clinically relevant difference of -3.25 points. The TuG 3-metre test saw an average performance improvement of 6.45%. This data provides promising evidence that the CUE1 represents a **viable approach** to effective treatment of movement symptoms in people with Parkinson's disease. Results will still need to be reproduced in a clinical setting before its effectiveness can be authenticated, and generalised across a wider population, but this report provides a strong motivation for the selection of this device for further clinical trials.