

CogiMotion Trial

Post-Market Clinical Analysis

Single-Session Feasibility Study — Participant & Therapist Feedback

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Trial hosted at: Hobbs Rehabilitation Bristol

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Participant Demographics and Study Context

The single-session feasibility study enrolled five participants (four male, one female) with ages ranging from 28 to 83 years (mean approximately 65.8 years). All participants had sustained ischaemic stroke, with lesion locations spanning right hemisphere, left hemisphere, cerebellar and brainstem regions. Time since stroke occurrence varied considerably, from 14 to 95 months, representing both sub-acute and chronic phases of recovery. Living situations included cohabitation with family (n=4) and living alone (n=1), while baseline therapy ranged from 0 to 3 hours per week. This demographic profile indicates that the device was tested across a meaningfully diverse sample with respect to age, stroke chronicity and level of functional impairment, lending preliminary breadth to the feasibility findings.

Participant-Reported Outcomes and Experience

Participant feedback was captured via structured Likert-scale ratings (1–10) across eight usability and experience domains. Comfort with the device was rated highly across the cohort (mean 9.0/10, range 7–10) and all five participants reported an absence of discomfort or safety concerns (10/10 across the board). Overall satisfaction was similarly strong (mean 9.4/10), suggesting positive initial acceptance of the CogiMotion in a clinical rehabilitation setting. Ease of daily routine integration also scored well (mean 8.4/10), indicating that participants perceived the system as compatible with ongoing home or therapy schedules. Motivation and stimulation during sessions scored a mean of 7.4/10, with one participant rating this as low as 5, suggesting that while most users found the experience engaging, the motivational design may benefit from refinement (particularly for patients with limited comprehension of the game mechanics). Perceived effectiveness for rehabilitation was the lowest-rated domain (mean 5.4/10, range 1–8), reflecting uncertainty among some participants about the therapeutic value of a single session and highlighting the need for improved patient training regarding the system's rehabilitative mechanisms.

Qualitative Participant Feedback

Open-ended comments from participants revealed both enthusiasm and areas of confusion. Several participants expressed genuine interest in the technology, with one noting the headset was very comfortable and that participation felt like a privilege. However, recurrent feedback pointed to a lack of clarity around the game's visual feedback. Specifically, what the building blocks represented, why they changed colour and how this connected to rehabilitation outcomes. One participant explicitly noted difficulty understanding the game objective and could not distinguish the clinical benefit of the block-building mechanic from the smiley-face feedback already provided by the Amadeo device. These comments suggest that while the physical interaction was well tolerated, the cognitive and motivational loop between the EEG-driven game feedback and the patient's understanding of their own motor intent requires clearer in-session explanation or more intuitive interface design.

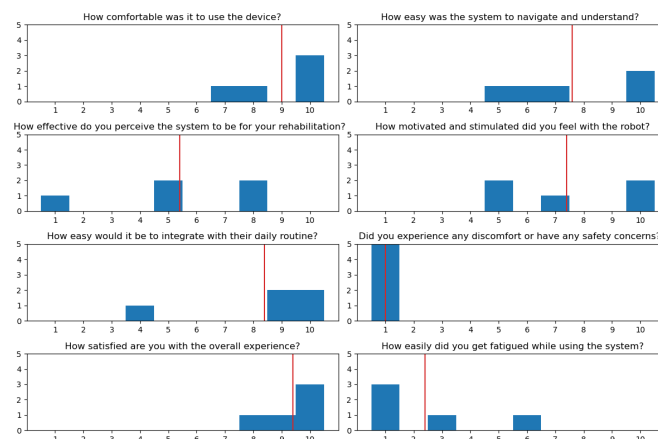


Figure 1: Feedback responses from the stroke-survivor participants

Therapist-Reported Outcomes and Clinical Utility

Therapists rated the relevance of movements to rehabilitation goals most highly (mean 9.6/10), affirming strong clinical face validity. Safety was also rated favourably (mean 9.2/10) and workflow integration scored well (mean 8.6/10), indicating that clinicians saw the device as readily adoptable within existing rehabilitation protocols. Session benefit was rated at a mean of 7.8/10, reflecting a generally positive but measured view of clinical impact within a single-session context. The lowest therapist ratings were for the patient-review interface (mean 6.4/10) and therapy delivery efficiency (mean 7.2/10), suggesting that the clinician-facing dashboard and data output tools would benefit from further development. This is a point echoed in qualitative feedback where one therapist expressed interest in knowing what data could be extracted, such as time spent moving with intent.

Qualitative Therapist Feedback and Clinical Observations

Therapists provided substantive qualitative commentary that reinforced the quantitative findings. A consistent theme was the clinical value of EEG-based motor intent monitoring: one therapist noted that without CogiMotion, they would not have known how attentive the participant truly was during the task and that this visibility provided reassurance of clinical benefit and justification for continuing therapy. Therapists also observed that participants responded well to verbal cueing and encouragement, which correlated with in-game performance, reinforcing the feedback loop between therapist input and the Cogigame system. Suggestions for improvement included implementing a familiarisation or trial period so patients could observe the difference in block-building when engaged versus disengaged, offering digit-isolation modes within the game for higher-functioning patients and providing clearer data outputs to clinicians.

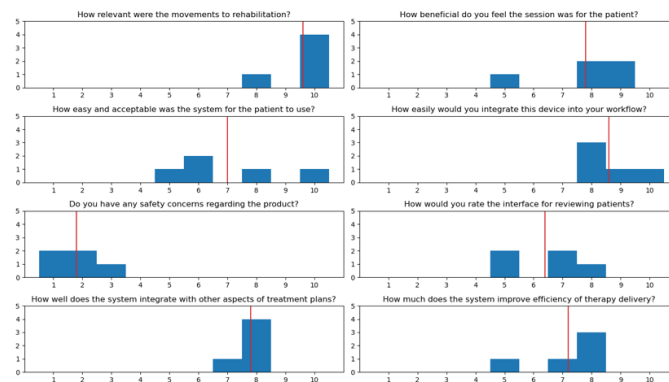


Figure 2: Feedback responses from the therapists

Session Tolerability and Safety

Of the five sessions, three were completed in full with durations of 15 to 27 minutes. One session was paused by the research practitioner to adjust the robot's range of motion after observing an increase in finger range of movement and was then recommenced at the progressed settings. And one session was ended at the participant's request due to fatigue after approximately 15 minutes. Pre-session fatigue scores ranged from 0 to 5, with post-session scores ranging from 0 to 5, indicating that while some participants did experience increased fatigue, no participant reported a disproportionate or unexpected escalation in fatigue beyond their baseline. No serious adverse events, pain or device-related injuries were reported. All participants tolerated the EEG headset and robotic interface well, and therapists consistently described participants as engaged throughout the sessions, even when rest breaks were required. These findings support an acceptable safety and tolerability profile for the CogiMotion in a supervised clinical setting.

Summary and Implications for Post-Market Surveillance

The single-session feasibility data indicate that CogiMotion is well tolerated, safe and positively received by both patients and therapists in a post-stroke rehabilitation context. Comfort, satisfaction and safety ratings were consistently high and therapists identified meaningful clinical utility (particularly the ability to monitor motor intent via EEG in real time, which provided objective evidence of patient engagement not otherwise available).

Key areas for improvement identified through this post-market feedback include:

1. Enhancing the clarity of in-game visual feedback for patients
2. Enriching clinician-facing data outputs and the patient-review interface
3. Refining signal stability

These findings should inform iterative product development and will serve as a baseline against which future multi-session and larger-scale post-market studies can be benchmarked.