

Patient and technical feasibility of real-world sampling of cognition and functional neurophysiology in ALS and FTD

PRECISION ALS



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Cumulus Real-World Neurophysiology Platform

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Cumulus provides full service:

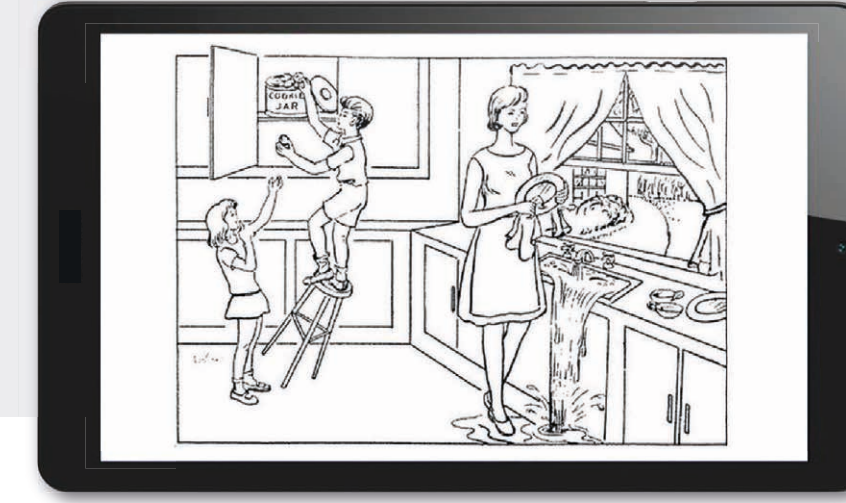
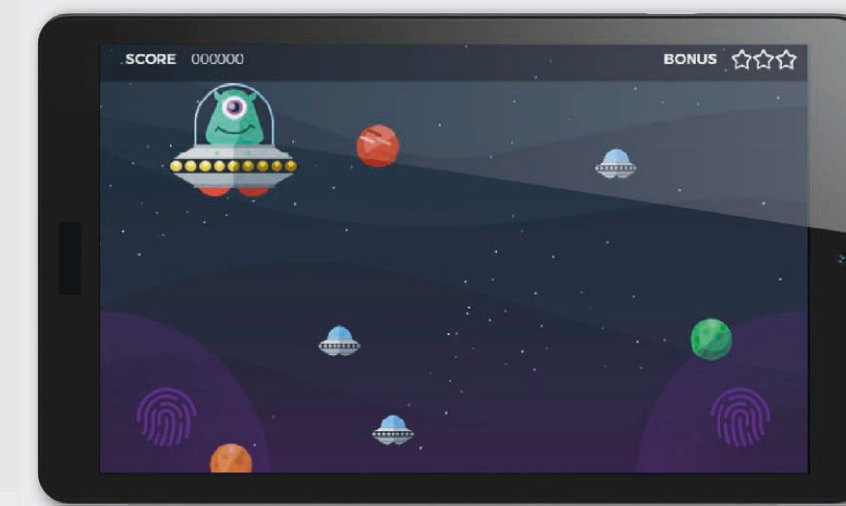
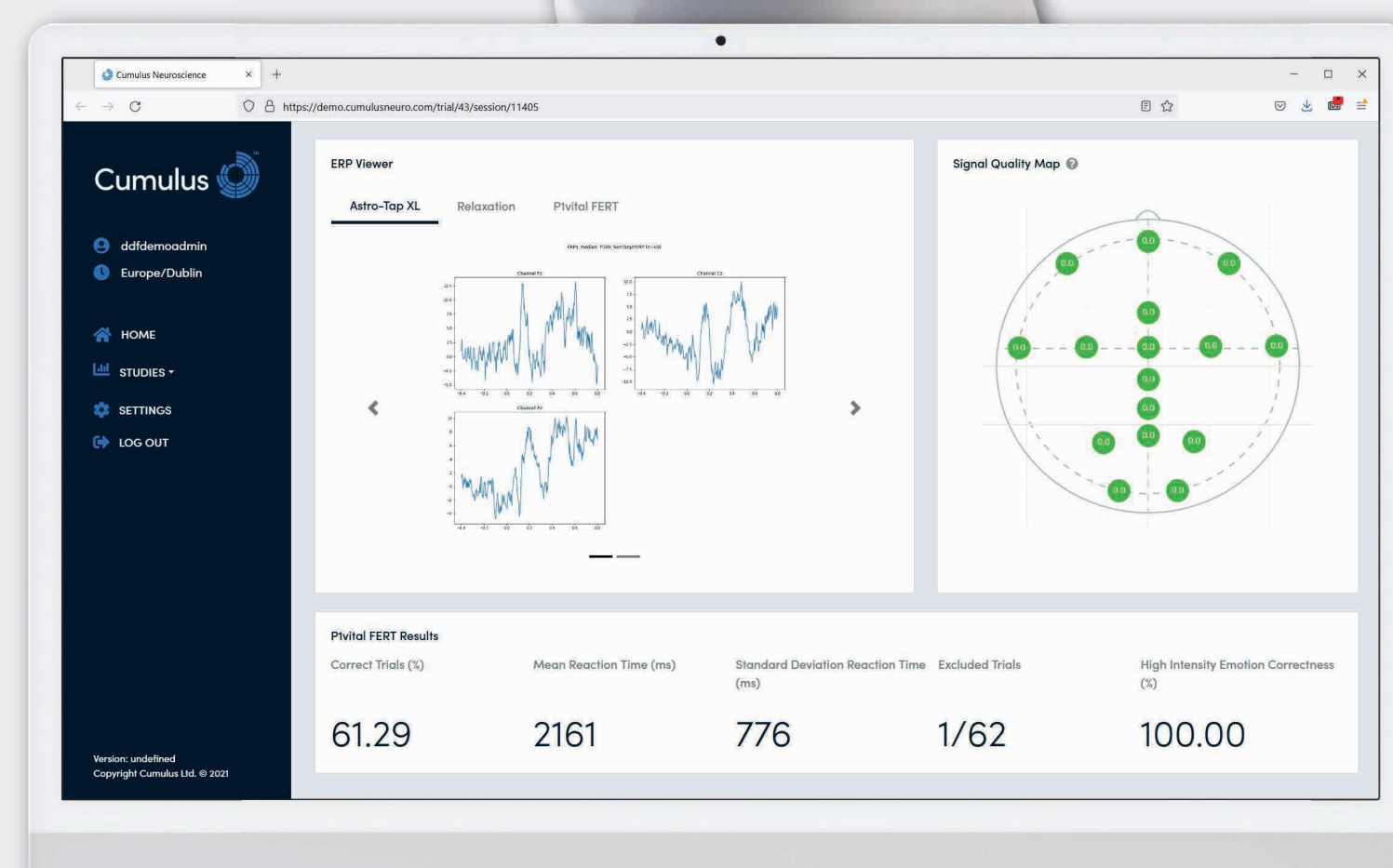
- Protocol/study/SAP design
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- Reporting and custom analytics

Certified Medical Device

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Background

Clinic-based assessments can be effective in tracking disease progression in clinical research, but do not scale to support public health needs or large-scale real-world studies.

Novel digital platforms suitable for home use are scalable, yielding frequent, real-world data, but their usability must be demonstrated in patient populations suffering from cognitive and motor impairments, and behavioural changes.

Study Objective

To characterize the feasibility of the Cumulus neurocognitive platform for repeated at-home use by FTD and ALS patients, and age-matched controls.

Methods

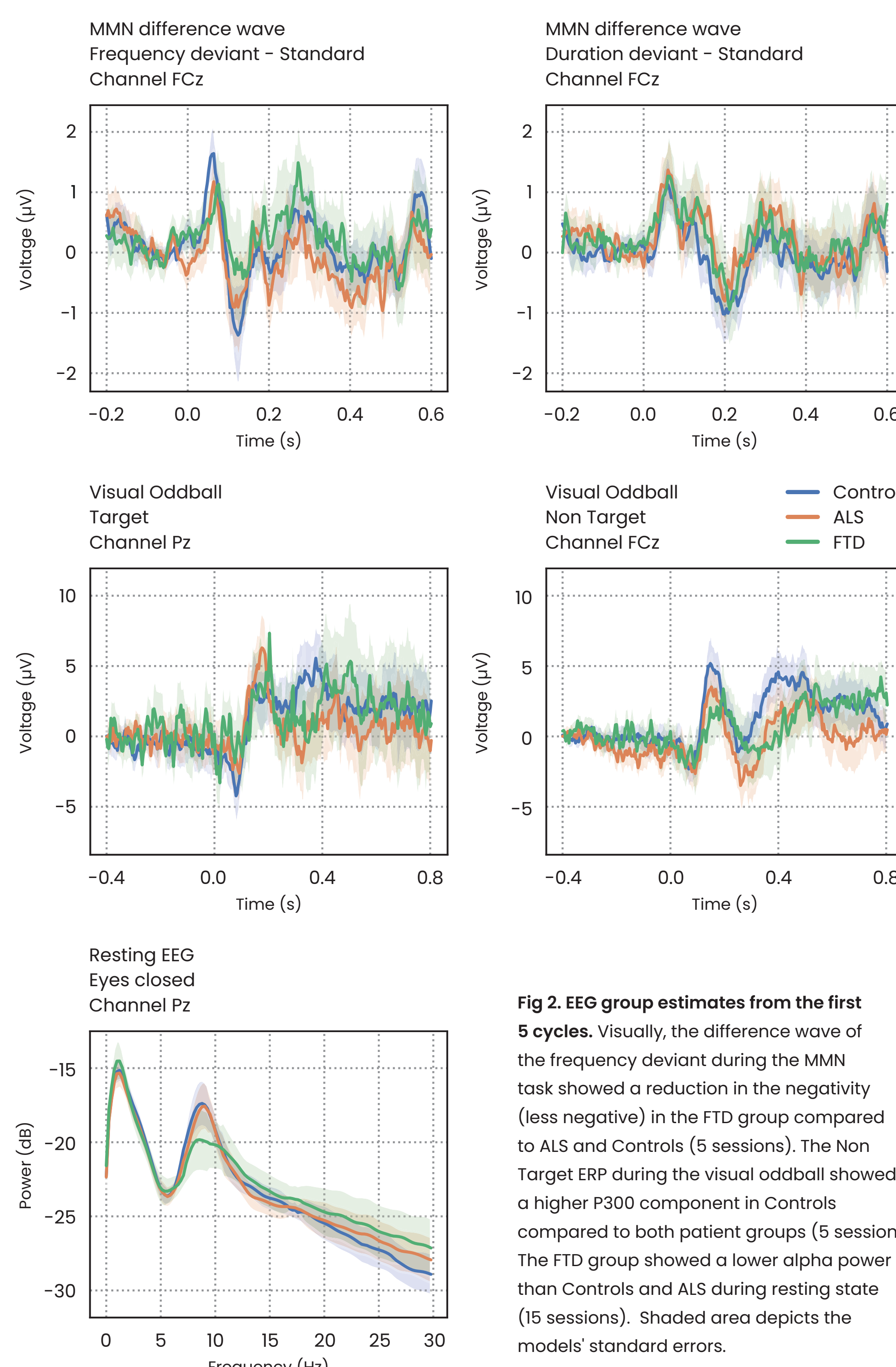
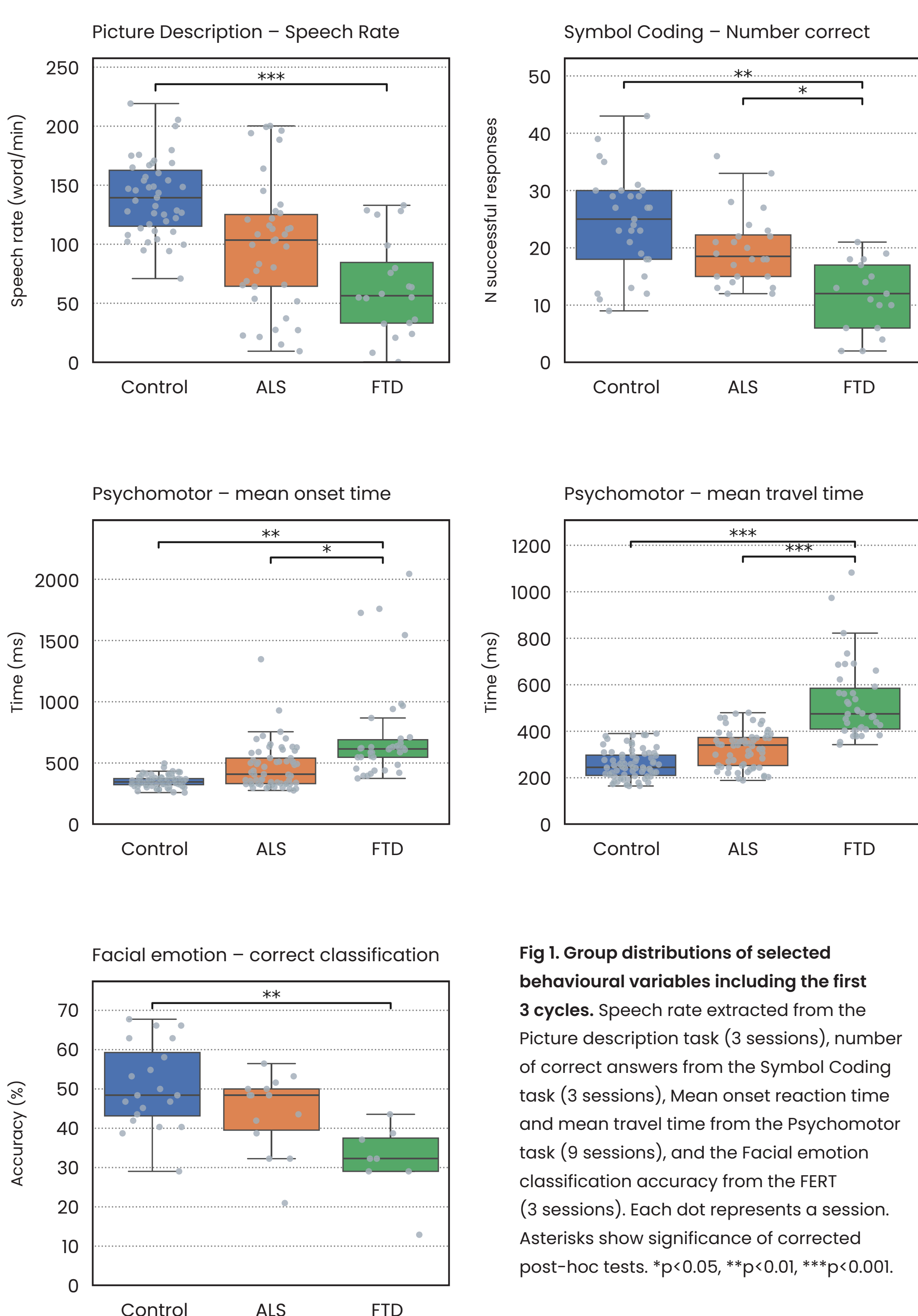
- Participants completed cycles of three 25-min sessions every two weeks in the home for 8 months, with the Edinburgh Cognitive and Behavioural ALS Screen (ECAS) composite score being collected at month 0, 4 and 8.
- The cycles comprised digital gamified tasks, including 4 behavioural tasks (Picture Description, Symbol Coding/Digit Symbol Substitution Task, Facial Emotion Recognition Task/FERT, Psychomotor Speed) and 3 EEG tasks (Resting State/RS, Mismatch Negativity/MMN, Visual Oddball).
- The Psychomotor task and the Resting State were scheduled in every session of the cycle. Other tasks were scheduled once per cycle.
- EEG was self-recorded with the 16-channel dry EEG Cumulus headset.
- Adherence to-date was computed across the entire study protocol.
- Interim cross-sectional analyses of behavioural endpoints were computed across the first 3 cycles: mixed-effect models were fitted with patient group as a fixed effect and user as a random effect.
- We analysed EEG data extracted from the Visual Oddball and MMN tasks, and from Resting State recordings (2min, eyes closed).
- Power spectral density during Resting State was calculated per session using Welch's method. Median ERPs from the Visual Oddball and MMN tasks were calculated per session. The MMN difference wave was calculated per session.
- EEG group estimates were obtained from robust mixed models with user as a random effect. Models were fitted respectively per timepoint or frequency bin to the session level ERPs or power spectral density.

Demographics

	ALS	FTD	Controls
Number of participants	11 recruited 2 withdrawals	8 recruited 1 withdrawal 1 screen failure	10 recruited 0 withdrawals
Age in years [mean, (std, range)]	62.9 (8.8, 47-74)	65.6 (8.6, 54-76)	63.7 (9.7, 42-75)
Gender	9 females/ 2 male	2 females/ 5 males	6 females/ 4 males
ECAS [mean, (std)]	102.4 (7.9)	86.9 (22.7)	115.8 (9.8)
% Total Adherence [mean, (std)]	45.6 (30.02)	59.1 (35.33)	76.5 (25.24)
% Adherence 1st session of the cycle [mean, (std)]	59.6 (28.88)	75.2 (32.92)	91.1 (16.4)

Table 1. Demographics and adherence data.

Results



Conclusions

Conclusions Interim analyses from this first-in-class study suggest that older individuals, and those with FTD and ALS are able to participate in home-based studies with intensive repeated sampling protocols. Data has similar morphology and exhibits patterns as expected based on literature. Initial examination of the data suggests that digital remote measurements can separate groups, constituting positive initial evidence for task validity and technical feasibility.

References

1. McWilliams EC, Barbey FM, Dyer JF, et al. (2021) 'Feasibility of Repeated Assessment of Cognitive Function in Older Adults Using a Wireless, Mobile, Dry-EEG Headset and Tablet-Based Games.' *Front Psychiatry*
2. Beeldman, E. et al. (2018) 'The cognitive profile of behavioural variant FTD and its similarities with ALS: a systematic review and meta-analysis', *Journal of Neurology, Neurosurgery & Psychiatry*



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