

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

PRECISION ALS



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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 are scalable, but their usability must be demonstrated in patient populations suffering from cognitive and motor impairments, and behavioural changes.

Methods

10 ALS, 10 FTD, and 10 age-matched controls (recruitment w/ replacement)

8 months repeated sampling

Set of three 25-min sessions every two weeks in the home

Digital gamified tasks: Language, Digit Symbol Substitution Task (DSST), Associative Memory, Oddball and Psychomotor task

16-channel dry EEG Cumulus headset

Adherence was computed across the entire study protocol. Interim cross-sectional analyses of behavioural and EEG endpoints were computed across the 5 first sessions: linear mixed-effect models with a fixed effect for patient group.

Results

	ALS	FTD	Controls
Number of participants	11 recruited 2 withdrawals	8 recruited 1 withdrawal	10 recruited 0 withdrawal
Age in years [mean, (std, range)]	61.4 (9.0, range: 47-74)	65.7 (8.8, range: 54-77)	63.9 (9.8, range: 42-76)
Gender	8 females/1 male	2 females/5 males	6 females/4 males
% Adherence	46.1%	61.8%	72.5%
ECAS [mean (std)]	102.4 (7.9)	86.9 (22.7)	114.8 (9.8)

Table 1. Demographics and adherence data.

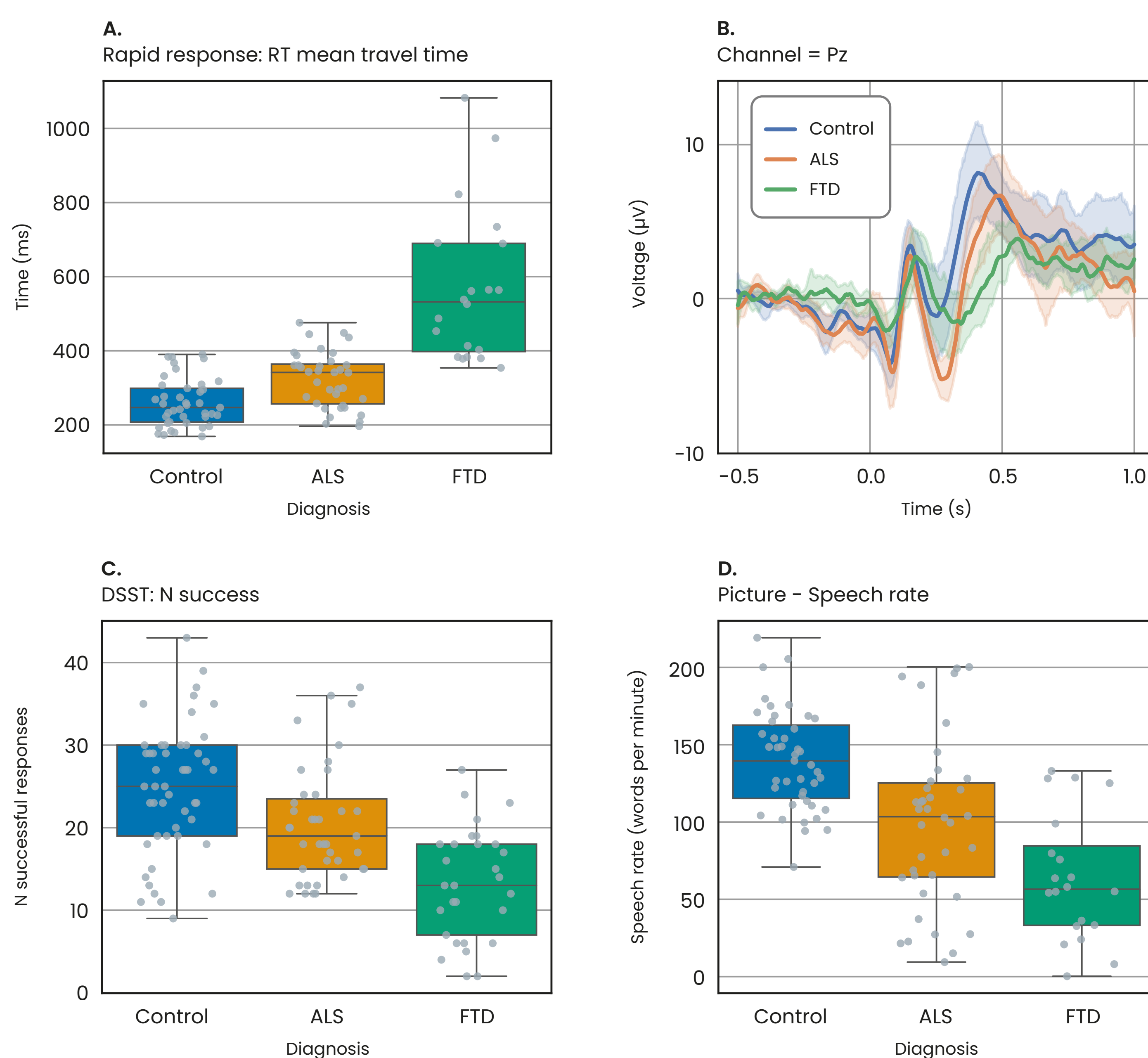


Fig 2. A. Reaction time extracted from the Psychomotor task. B. Non-Target P300. Events related potentials extracted from the gamified oddball task at channel Pz. C. Number of success in the DSST. D. Speech rate extracted from the picture description task. Controls: N=10, ALS: N=9, FTD: N=7. Each dot represents a session.



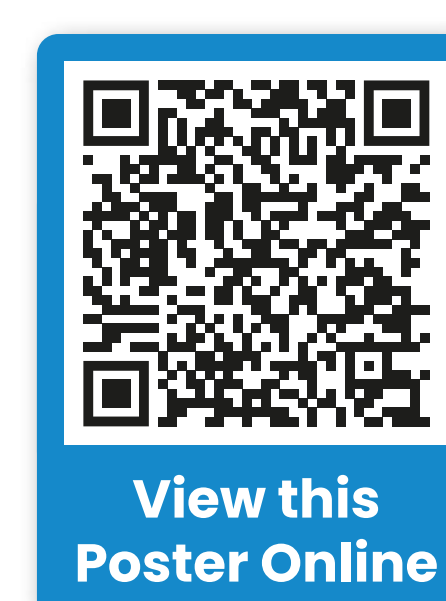
Fig 1. The Cumulus platform. From left to right, Top row: The Cumulus 16-channel dry EEG headset and the online dashboard for remote study monitoring. Middle row: Screenshots of the gamified Digit Symbol Substitution and Oddball tasks. Bottom row: Screenshots of the Psychomotor and Language & Speech tasks.

Behavioral and EEG Data Analyses

- Main effect of patient group in the travel time of the Psychomotor task ($F(2, 21.2)=21.4, p<0.001$), in the number of successful responses in the Digit Symbol Swap task ($F(2, 24.1)=6.8, p=0.005$) and in the speech rate of a picture description task ($F(2, 24.4)=6.9, p=0.004$).
- Post-hoc tests showed that the FTD patients had a longer travel time (Psychomotor) than controls ($t(21.6)=-6.4, p<0.0001$) and ALS ($t(21.6)=-5.1, p=0.0001$).
- The FTD group had fewer correct responses (Digit Symbol Swap) than controls ($t(23.9)=3.7, p=0.0036$).
- Speech rate was higher in controls compared to FTD ($t(24.6)=3.6, p=0.0039$) and a trend was observed compared to ALS ($t(23.8)=2.4, p=0.079$).
- No main effect of patient group was found in the associative learning task, nor in the total speech duration of the picture description task.
- Visual inspection of the Non-Target P300 event-related potential (ERP) suggests a reduction of amplitude and increase in latency of this ERP in the FTD and ALS group.

Conclusions

Interim analyses from this first-in-class study suggest that those with FTD and ALS are capable and willing to participate in home-based studies with intensive repeated sampling protocols of behaviour and functional neurophysiology. Initial examination of the data suggests that digital remote measurements can differentiate the groups, constituting positive initial evidence for task validity and technical feasibility.



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