Feasibility and reliability of real-world functional neurophysiology with at-home use of Cumulus' wireless EEG

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Cumulus Real-World Neurophysiology Platform

Developed in collaboration with leading pharma companies and KOLs

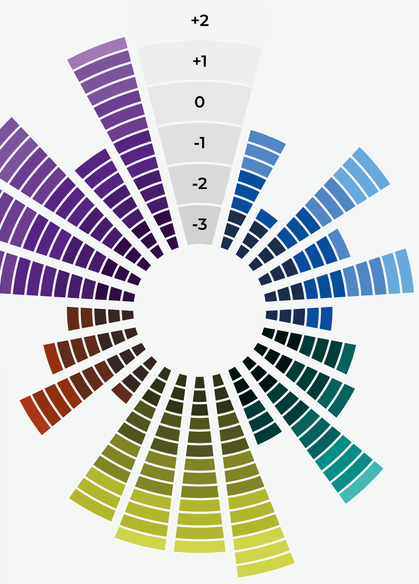
Cumulus provides full service:
- Protocol/study/SAP design
- On-site training, off-site support
- Full data package
- Reporting and custom analytics

Certified Medical Device

Designed for and with patients and clinicians

Secure automatic upload and QC

Real-time dashboard monitoring of decentralized and home-based data collection.



Cognition
Episodic memory, executive function

EEG
Neuronal integrity, network connectivity

Sleep
Sleep quality metrics, sleep staging

Mood
Emotional bias, atypical mood

Language
Vocabulary, language, organisation, prosody

Introduction

- The recent focus on running decentralised clinical trials has accelerated adoption of methods for "virtual" trials
- Remote survey and digital endpoints may lack objectivity, scientific validation, and grounding in the brain
- Brain imaging and robust cognitive testing still require visits to larger clinics and research centres
- Functional EEG is a technology that can scale to real-world studies, and is clinically informative in neurodegeneration and psychiatry

Research Questions

Q1: Is unsupervised at-home use of functional neurophysiology feasible?

We compare adherence across several real-world studies with controls and patients, and evaluate endpoints for construct validity.

Q2: How do noise levels compare to clinic-based data?

We compare home recorded ERP data to that from a gold-standard benchmark dataset (ERP CORE, Luck Lab, UC Davis)

Q3: How reliable are real-world neurophysiological end-points?

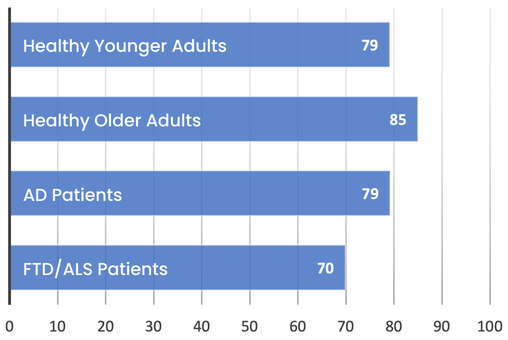
We calculate Intra-Class Correlation, a measure of test-retest reliability, across repeated in-clinic and at-home sessions

Methods & Results

Q1: Is unsupervised at-home use of functional neurophysiology feasible?

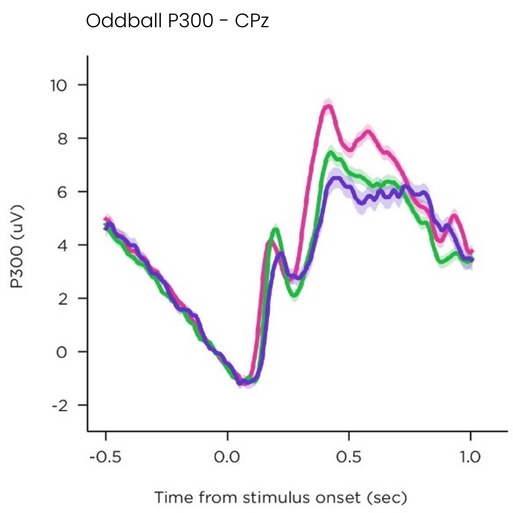
Across a number of representative studies, participants were briefly familiarized with the platform, in-person, during enrolment. Control participants, young (av. 26yrs) and old (av. 68yrs), and patients (AD and ALS/FTD), were asked to carry out a series of short (<30m) at-home sessions, repeatedly over a number of months. Adherence data is shown for first 10 at-home sessions. Data for patients are preliminary for studies which are still recruiting. Patients may have assistance of study partner for at-home setup of headset and tablet.

At-home unsupervised adherence (%)



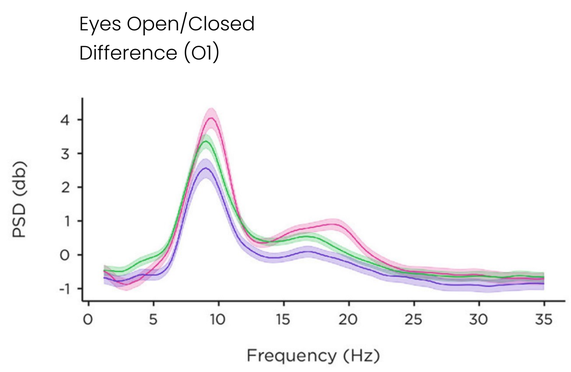
Effect of age (n=89 healthy older adults)

Oddball P300 - CPz



Oddball Target ERP

Eyes Open/Closed Difference (O1)



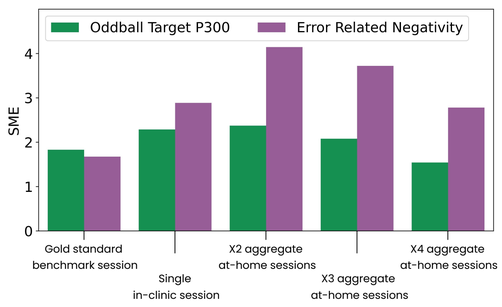
Resting state qEEG

Q2: How do noise levels compare to clinic-based data?

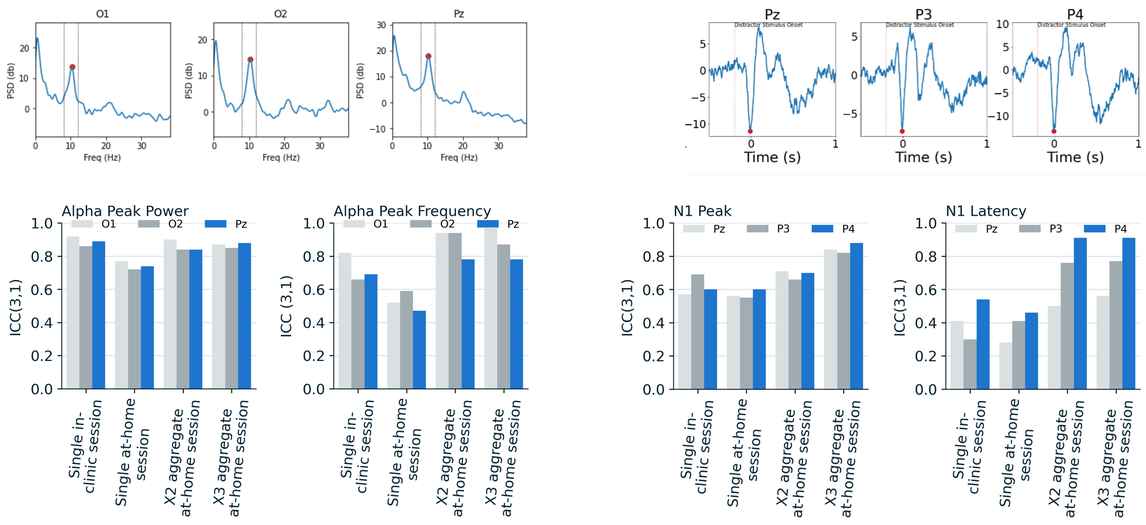
Noise measures from gamified visual oddball and gamified flanker task are compared to a clinic-collected gold-standard benchmark (wet EEG and conventional lab tasks).

N=30 young adult healthy participants

Standardized Measurement Error



Q3: How reliable are real-world neurophysiological end-points?



ICC for automatically extracted qEEG power and frequency measures, during a tablet-based resting task paradigm.

ICC for automatically extracted visual ERP amplitude and latency measures, during a gamified flanker task app.

Conclusions

- Older and younger users, including those with a neurological condition, are willing and able to perform short repeated sessions of functional neurophysiology in the home over weeks and months
- Predicted group-level contrasts can be seen at grand-average level, even for subtle changes due to natural aging
- Signal quality and test-retest reliability from a single gamified dry EEG session lags that seen in a conventional clinic setup, but can be compensated for by aggregating over a handful of at-home sessions
- This approach provides a resolution to the dilemma of choice between the quality of clinic-based measures, and quantity of scalable measures
- Pharma precompetitive studies are underway to further validate this approach with longer studies and in relevant patient populations

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