

A longitudinal real-world study in patients with Alzheimer's Disease dementia using frequent multi-domain digital measurements at-home performed on the Cumulus NeuLogiq™ Platform: usability and feasibility findings

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Cumulus NeuLogiq™ platform for use in real-world settings

Developed in collaboration with leading pharma companies and KOLs (below).

Cumulus provides full service:

- Protocol / study / SAP design
- On-site training, off-site support
- Data package
- Reporting and custom analytics

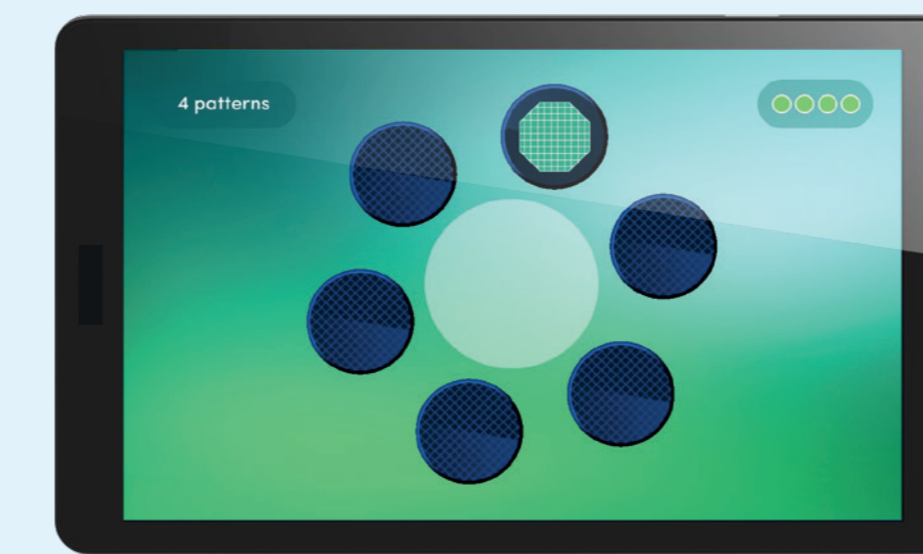
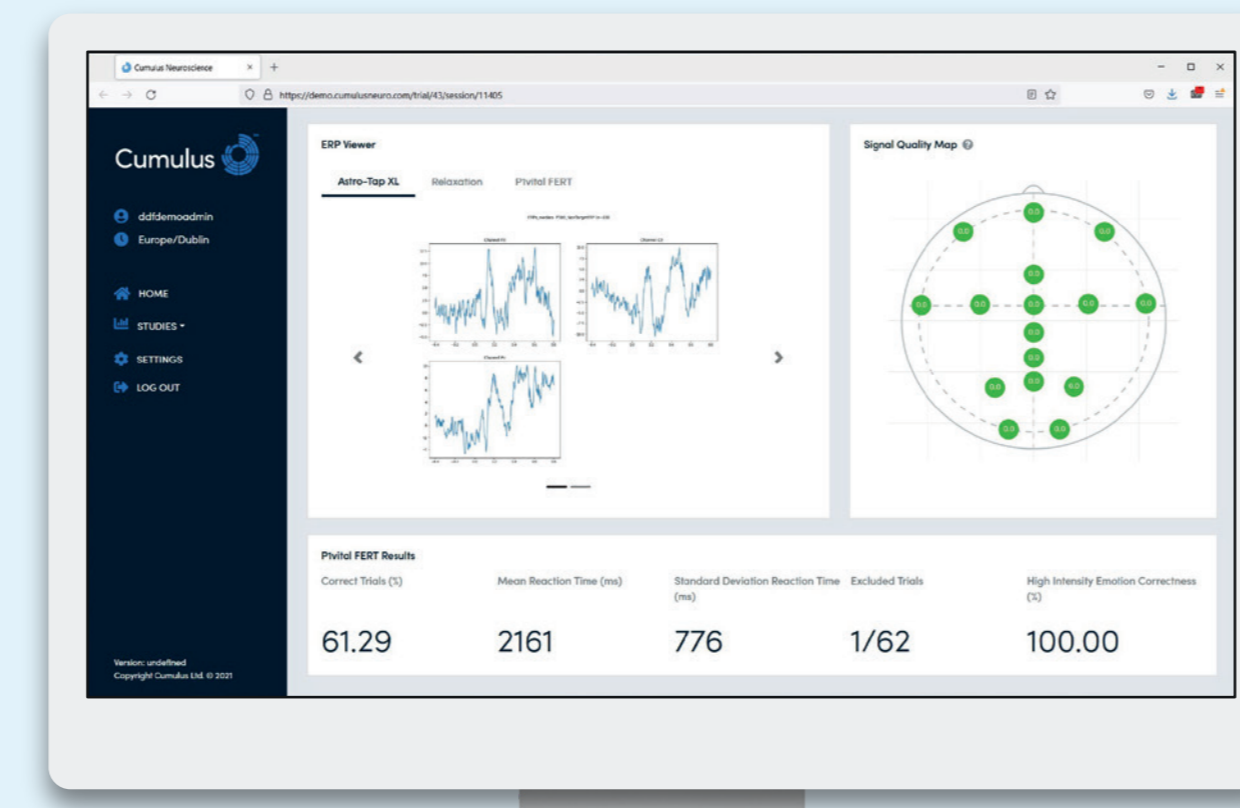
Audit ready including FDA 510(k), UKCA, HIPAA, GDPR, ISO13485.

Designed for and with patients and clinicians, deployed in Phase 0-1b CNS trials.

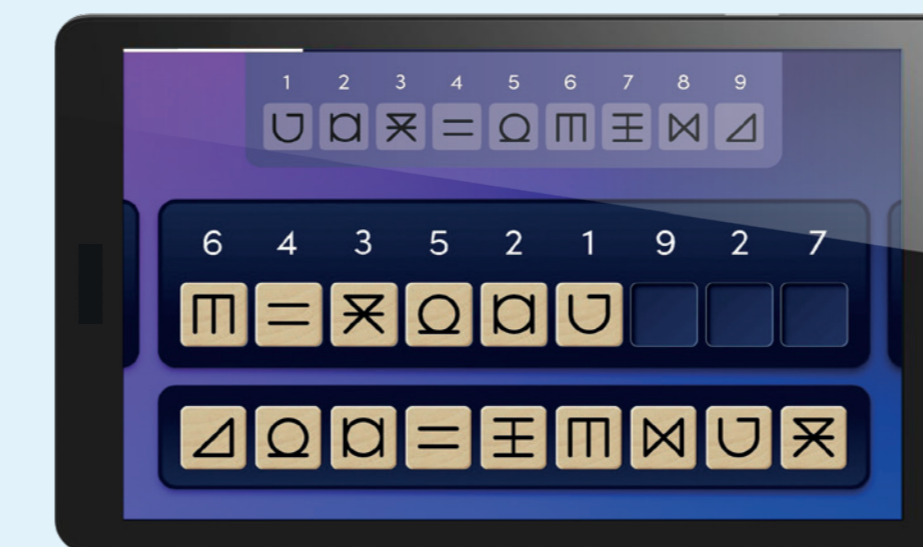
Secure automatic upload and QC. Real-time dashboard monitoring of decentralized and home-based data collection.

Cumulus cognitive and EEG / ERP tests are designed to be highly repeatable, with large banks of non-repeating stimuli.

- Objectively administered and automatically scored
- Results (including EEG metrics) available in minutes, enabling remote monitoring and QC
- Suitable for detecting change over time



Memory Match: visual associative memory



Symbol Swap: digit symbol substitution/coding task



Continuous engagement with patients informs task design

Patient Advocate User Panel members are chosen for their experience with dementia, depression, schizophrenia and other neurological conditions. Each group includes a mix of patients, family members, and healthcare professionals.

Key Activities:

- Focus groups
- Usability testing
- User scenario simulation
- In-clinic sessions
- Remote sessions
- Study schedules

Outcomes may influence:

- Task development
- Hardware selection
- Onboarding procedures
- Session/task list features
- Study scheduling features
- Site staff training
- Participant facing materials



Introduction

- Many outcome measures used in AD clinical trials are paper-based and require clinic visits, making them infrequent and burdensome 'snapshots', subject to rater bias.
- Digital biomarkers may provide the ability to collect clinically meaningful data at scale, outside the clinic.

- A consortium of 10 pharma companies (above) came together with Cumulus Neuroscience to design a solution for frequent, objective, real-world measurement across a range of domains.
- Here we present a study that examined the feasibility of asking patients with mild AD dementia to use the NeuLogiq Platform repeatedly at home for one year.

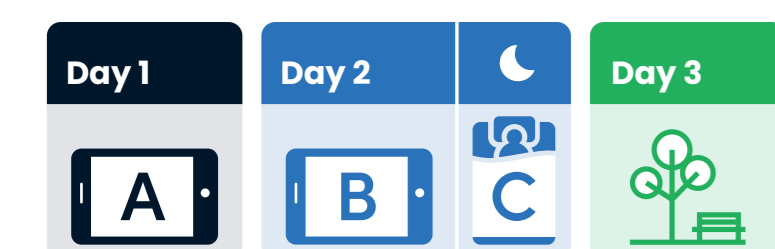
Methods

Study Protocol

- N = 59 Alzheimer's type mild dementia patients (ACE-III scores >60 and <88) and N = 60 matched cohort of controls recruited across 7 UK sites.
- Asked to use the platform during the day, as well as a sleep EEG device at night over a year at home.
- Day sessions consisted of completing 8 assessments on a mobile tablet consisting of behavioral tasks (memory, executive function, affective processing and language) overlaid with EEG.

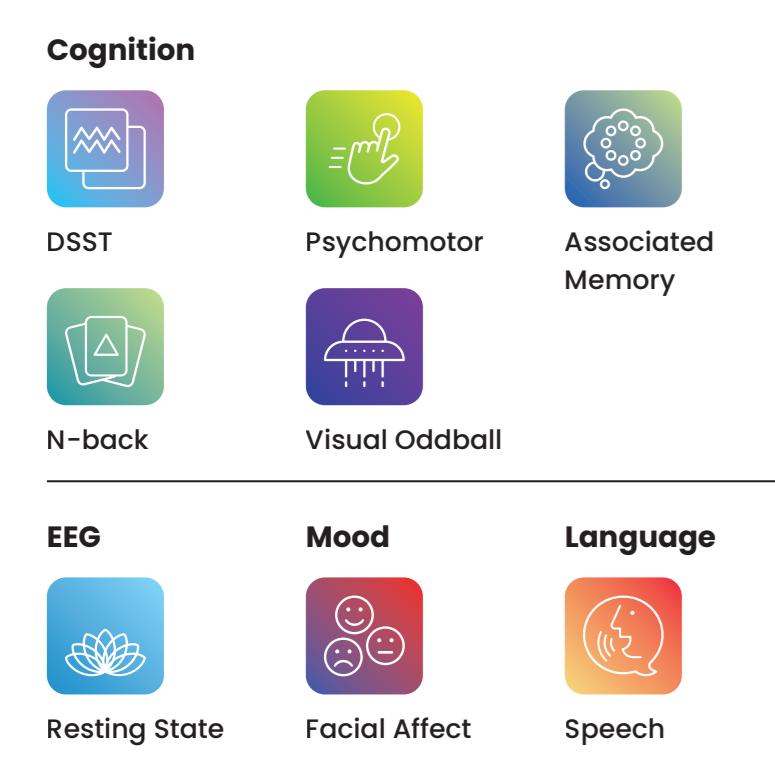
- A staggered longitudinal protocol followed with burst sampling tapering to periodic sampling over the year.
- Benchmark paper-based assessments (including ADAS-Cog) and self-reported usability were collected at months 0, 6, and 12.
- Blood plasma was collected at months 6 and 12 for later biomarker analysis.

Cycle



A cycle is made up of 3 consecutive days:
Day 1: Session A
Day 2: Session B, Session C (overnight)
Day 3: No Session
Sessions scheduled per cycle.
 In the 2-week burst stage, 5 cycles (15 sessions) are scheduled.

CNS 101 - AD Study
 60 Alzheimer's patients / 60 Older Healthy 12 months



Analysis

- Baseline demographics and pen-and-paper assessments from baseline were summarized per group.
- Session adherence was calculated using Stages 2-4. Withdrawals were included until the date of withdrawal. Session adherence was summarized per group and stage.

- Technology and Platform Feedback at baseline, week 2 and week 52 calculated per group and question
- Total number of sessions and hours of EEG collected at-home across 52 weeks.

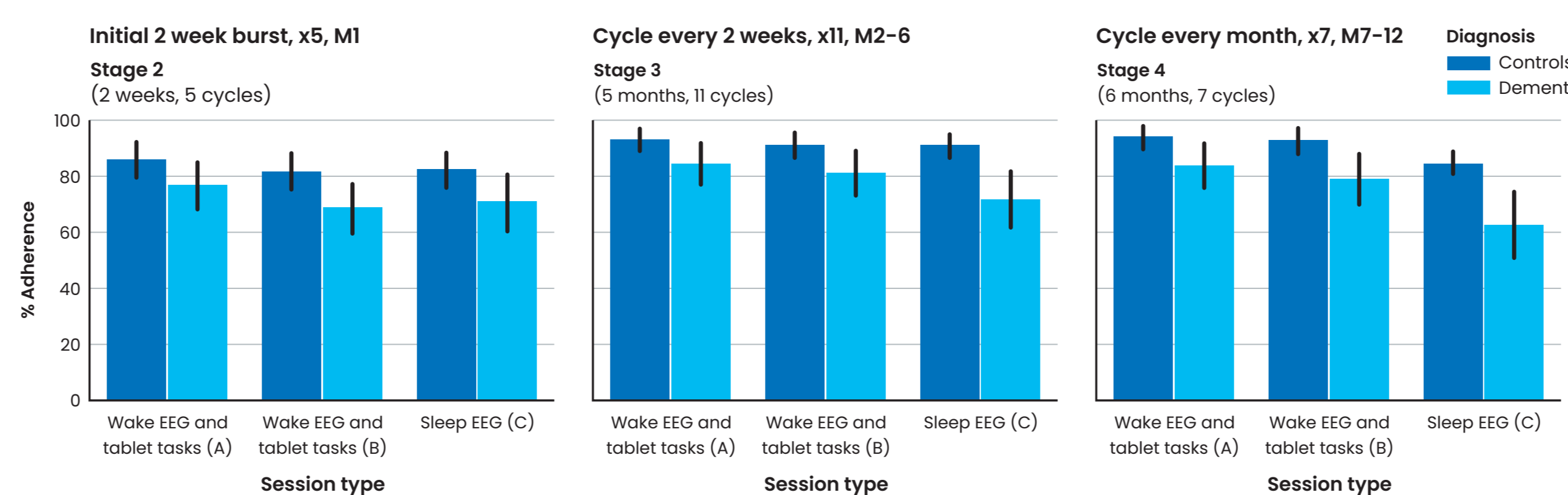
Results

Demographics, assessments and adherence

Variable	Descriptive	Dementia	Controls	Stat	Sig.	df	Effect size
Demographics							
Sex	males/females (ratio)	37:22 (1.68)	29:31 (0.94)	1.94	n.s.	1	-0.15
Education	left formal education before age 16	11	4	7.79	n.s.	5	-0.05
Education	left formal education at age 16	8	7				
Education	left formal education at age 17/18	11	14				
Education	To undergraduate degree or equivalent level	14	25				
Education	To Master degree or equivalent level	9	6				
Education	To PhD or equivalent level	6	4				
Age	mean (95%CI), n	73.8 (72.1, 75.5), n=59	71.2 (69.3, 73.0), n=60	-2.07	*	117	0.38
Assessments							
ADAS-COG	mean (95%CI), n	25.1 (23.0, 27.1), n=59	8.9 (7.7, 10.1), n=60	-13.55	**	117	2.48
NART	mean (95%CI), n	36.2 (33.9, 38.5), n=59	41.4 (40.2, 42.6), n=60	3.94	**	117	-0.72
Coding	mean (95%CI), n	37.9 (34.0, 41.5), n=59	56.7 (53.1, 60.4), n=60	7.1	**	117	-1.3
VPA	mean (95%CI), n	12.2 (10.7, 13.7), n=59	26.4 (24.7, 28.0), n=60	12.34	**	117	-2.26
Apathy motivation index	mean (95%CI), n	1.8 (1.5, 1.7), n=55	1.2 (1.2, 1.3), n=58	-4.41	**	111	0.83
Cantril's ladder - past	mean (95%CI), n	7.1 (6.5, 7.7), n=54	8.0 (7.7, 8.3), n=58	2.77	*	110	-0.52
Cantril's ladder - present	mean (95%CI), n	7.9 (7.4, 8.5), n=54	7.7 (7.3, 8.2), n=58	-0.57	n.s.	110	0.11
Cantril's ladder - future	mean (95%CI), n	6.0 (5.3, 6.7), n=54	7.5 (7.0, 8.0), n=58	3.52	**	110	-0.86
Depression scale (DASS)	mean (95%CI), n	6.9 (5.2, 8.6), n=54	3.4 (2.3, 4.5), n=58	-3.35	**	110	0.63
Anxiety scale (DASS)	mean (95%CI), n	5.3 (3.8, 6.8), n=54	3.2 (2.1, 4.2), n=58	-2.27	*	110	0.43
Stress scale (DASS)	mean (95%CI), n	9.6 (7.8, 11.6), n=54	6.3 (4.9, 7.7), n=58	-2.64	*	110	0.5
Geriatric depression score	mean (95%CI), n	3.5 (2.6, 4.4), n=56	1.1 (0.7, 1.5), n=58	-4.83	**	112	0.9
Sleep score (SCI)	mean (95%CI), n	7.3 (6.7, 8.0), n=55	7.5 (6.9, 8.0), n=58	0.25	n.s.	111	-0.05
SUS (Week 2)	mean (95%CI), n	54.5 (50.3, 58.6), n=41	63.8 (58.6, 69.1), n=53	2.62	*	92	-0.56
SUS (Week 52)	mean (95%CI), n	58.3 (51.5, 65.1), n=34	74.4 (70.1, 78.8), n=49	4.1	**	81	-0.89
Adherence							
Withdrawals	n	16	6				
Completers	n	43	54				
Adherence (Total)	mean (95% CI), n	78.3 (69.3-83.3) %, n=51	88.4 (83.5-93.2) %, n=57				
Adherence (Session A)	mean (95%CI), n	81.7 (74.6-88.8), n=51	91.1 (86.2-96.0), n=57				
Adherence (Session B)	mean (95%CI), n	76.8 (69.1-84.5), n=51	88.8 (83.7-93.8), n=57				
Adherence (Session C)	mean (95%CI), n	68.6 (59.6-77.7), n=47	85.6 (80.8-90.4), n=56				

Demographics of participants. Means and standard deviations (SD) of demographics and assessments per group. Non-paired t-tests were run for continuous variables, and X² tests were run for categorical variables. ADAS-Cog: Alzheimer's Disease Assessment Scale - Cognitive Subscale; NART: National Adult Reading Test; VPA: Verbal Paired Associates; SUS: System Usability Scale *p<0.05; **p<0.001; n.s.: non-significant.

Adherence per group and protocol stage



Group and protocol stage differences in adherence. The bar plot shows compliance to day-time sessions in both groups increases overtime. Session A completion was higher than Session B for both groups at each stage, with dementia patients displaying lower adherence to overnight sleep EEG sessions.

Total sessions and hours of EEG

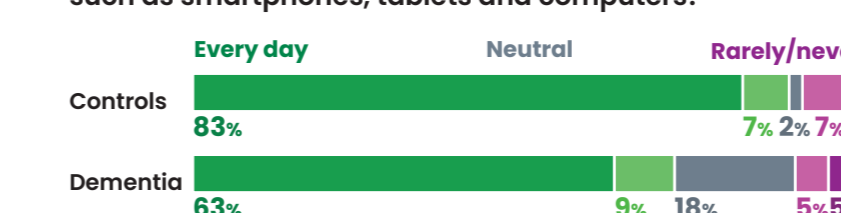
Variable	Descriptive	Dementia	Controls
Total Sessions (Opened)	n	2400	3285
Total Sessions (Complete)	n	2381	3263
EEG (wake; daytime)	days/hrs	23.89/573.3	28.43/682.2
EEG (sleep; overnight)	days/hrs	210.99/5063.7	315.08/ 7561.92

Accumulative total session and EEG data. 5644 total sessions were completed between both groups, with dementia patients contributing to 42% of the overall completed sessions. Over 52 days' worth of wake EEG and 526 days of sleep EEG was collected throughout the 52-week study period.

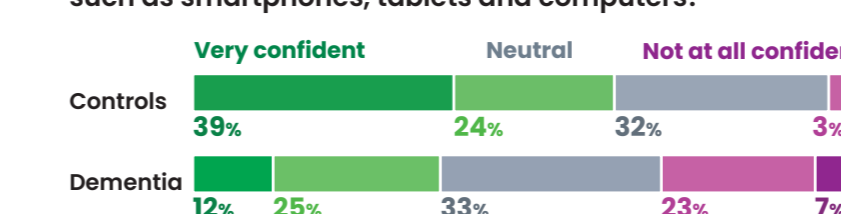
Technology and Platform Feedback

Baseline

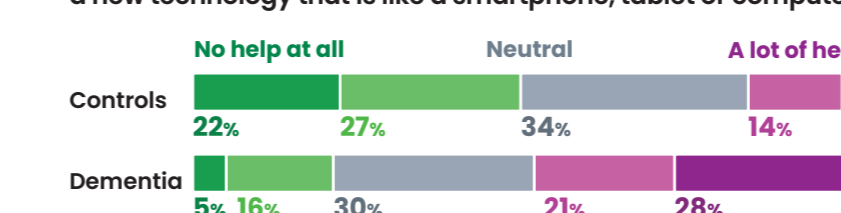
How often does the participant use technology such as smartphones, tablets and computers?



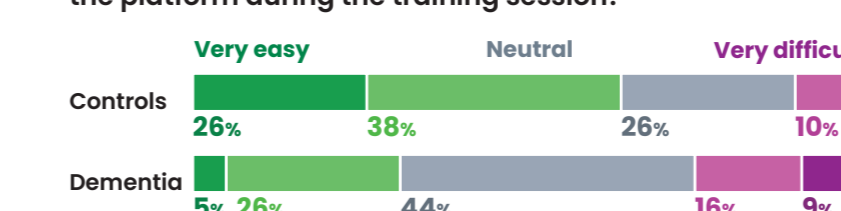
How confident do you feel about using technology such as smartphones, tablets and computers?



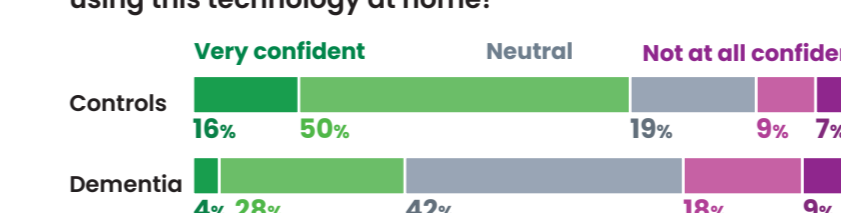
How much help do you feel you would need to get started with a new technology that is like a smartphone, tablet or computer?



How difficult/easy was it to learn how to use the platform during the training session?

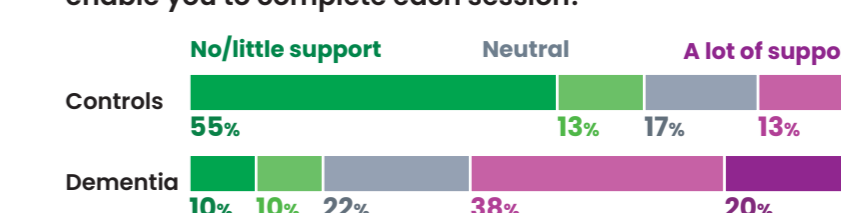


How confident do you feel about using this technology at home?

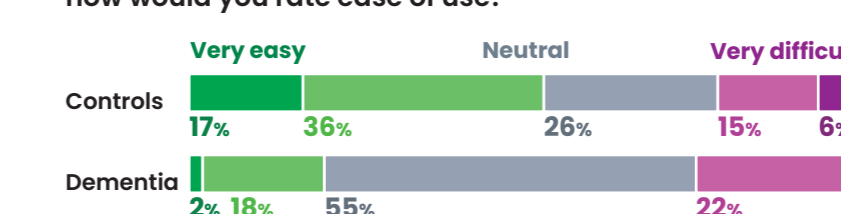


Week 2

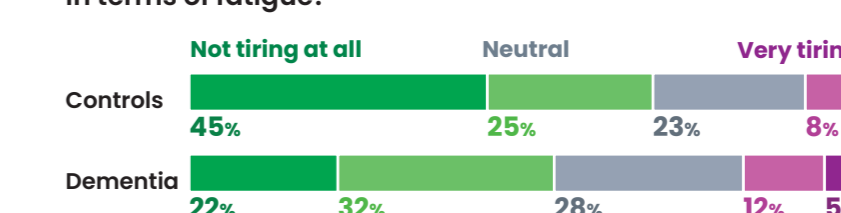
How much support was needed to enable you to complete each session?



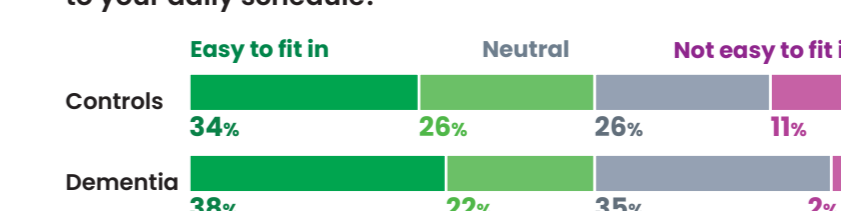
Thinking about the headset and tablet together, how would you rate ease of use?



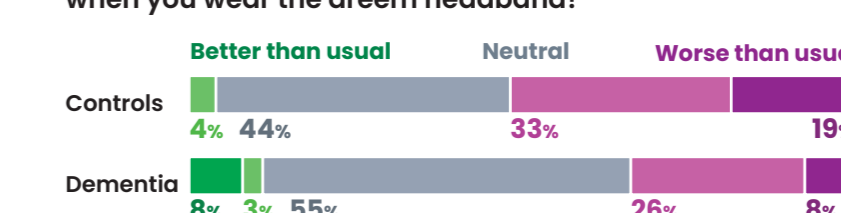
How do you find each session in terms of fatigue?



How well does the session fit in to your daily schedule?

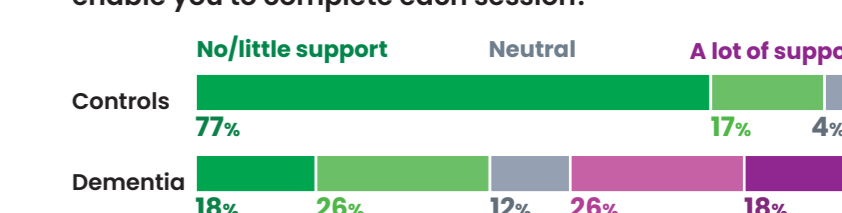


How is your sleep quality on the nights when you wear the dream headband?

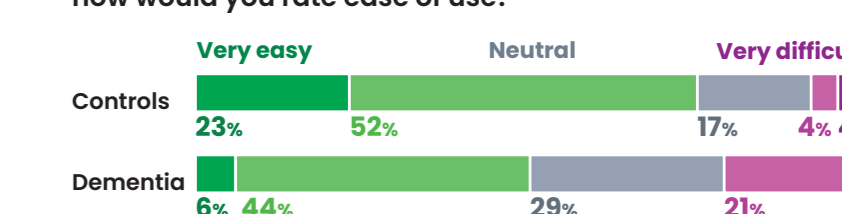


Week 52

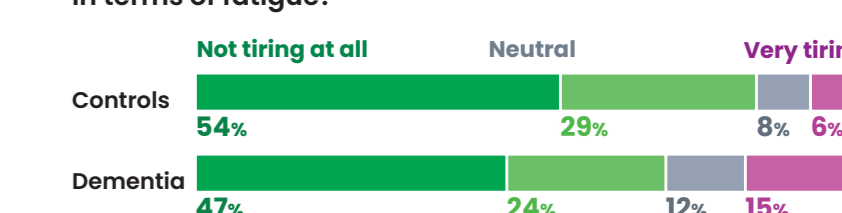
How much support was needed to enable you to complete each session?



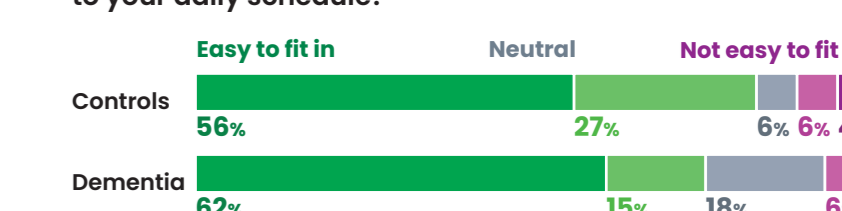
Thinking about the headset and tablet together, how would you rate ease of use?



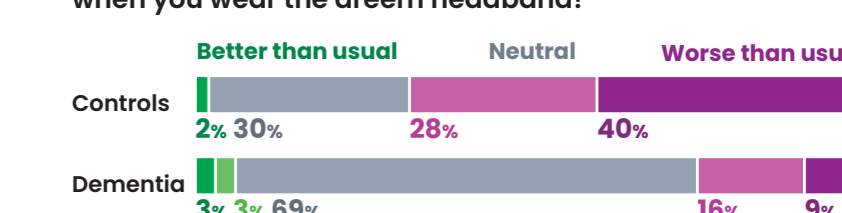
How do you find each session in terms of fatigue?



How well does the session fit in to your daily schedule?



How is your sleep quality on the nights when you wear the dream headband?



Most participants used technology, such as smartphones, tablets, and computers every day, with a higher percentage in the control group (83%) compared to the Dementia group (63%).

Controls reported feeling more confident using technology in general and the technology at home and require less support when using new technology than those with dementia.

Dementia participants reported requiring more support to enable session completion than Controls, with 68% of Controls reporting requiring little support compared to 20% of Dementia participants.

Only 24% of dementia patients found the headset and tablet difficult to use after 2 weeks of use, and more than half of the Control and Dementia group considered sessions not tiring and easy to fit in their daily schedule.

Following 52 weeks of use, there was a 150% increase in positive ease of use reported by dementia patients for the headset and tablet together, and a 24% decrease in participants requiring support to complete sessions.

Most participants did not find sessions to be tiring and found it easy to fit into their schedule (77% AD; 83% CN).

Note: Percentages per group may not total 100% due to rounding.

Conclusion

- The Cumulus NeuLogiq platform enables objective and frequent multimodal assessment and tracking of AD, in a manner that is practical for patients.
- Both participants living with Alzheimer's dementia (AD) and healthy controls exhibited high adherence to the protocol, contributing to a wealth of behavioral and EEG data despite initial reservations about using technology at home.
- Between weeks 2 and 52, dementia patients reported a 150% increase in ease of use of the EEG headset and tablet together and a 24% decrease in needing assistance to complete sessions, highlighting the platform's potential for successful integration into their daily lives.
- Further findings from the behavioral and EEG data collected can be found in the associated poster "Machine-learning analysis of real-world multimodal data collected autonomously at home detects dementia as precisely as a traditional composite scale" (Rueda-Delgado et al., AAIC 2024).

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