

1 year follow-up after Transcranial Pulse Stimulation in Alzheimer's patients

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Background

Transcranial Pulse Stimulation (TPS) is a therapy that uses shockwaves for the treatment of Alzheimer's Disease (AD). Recently, our group published short term clinical results after the first treatment cycle of 2 weeks (Cont et al. 2022). Here we analyze 1 year follow-up data.

Methods

A consecutive number of 25 TPS-treated patients was examined. All patients received 4 Hz TPS of about 6000 pulses of 0.2 mJ/mm² (navigated bifrontally, biparietally, bitemporally, and praecuneus) using the Neurolith System (Storz Medical). After the initial treatment cycle of 6 sessions over 2 weeks, patients were planned to receive monthly booster sessions. Cognitive scores were assessed (e.g. ADAS, MMST, MoCA) up to 6 (n = 10) and 12 months (n = 5).

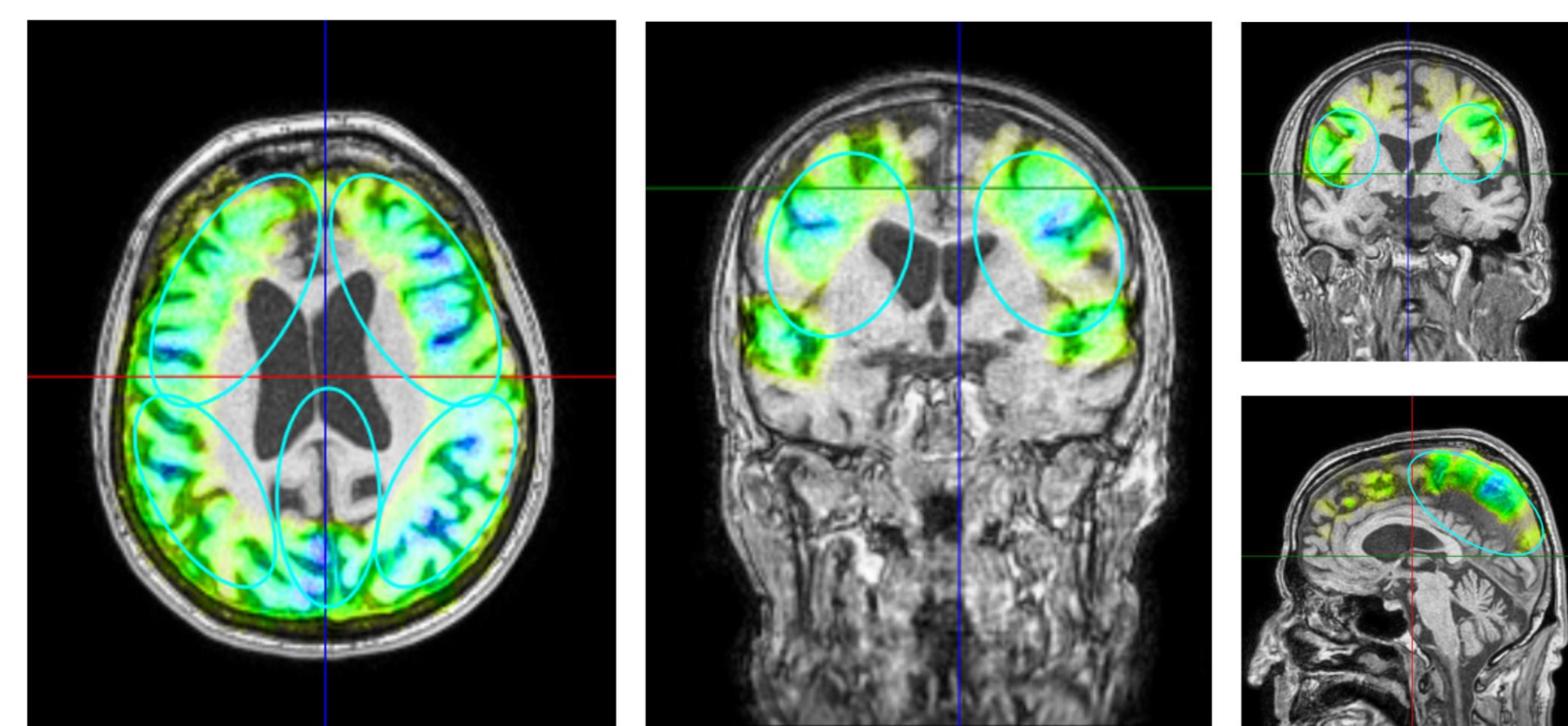
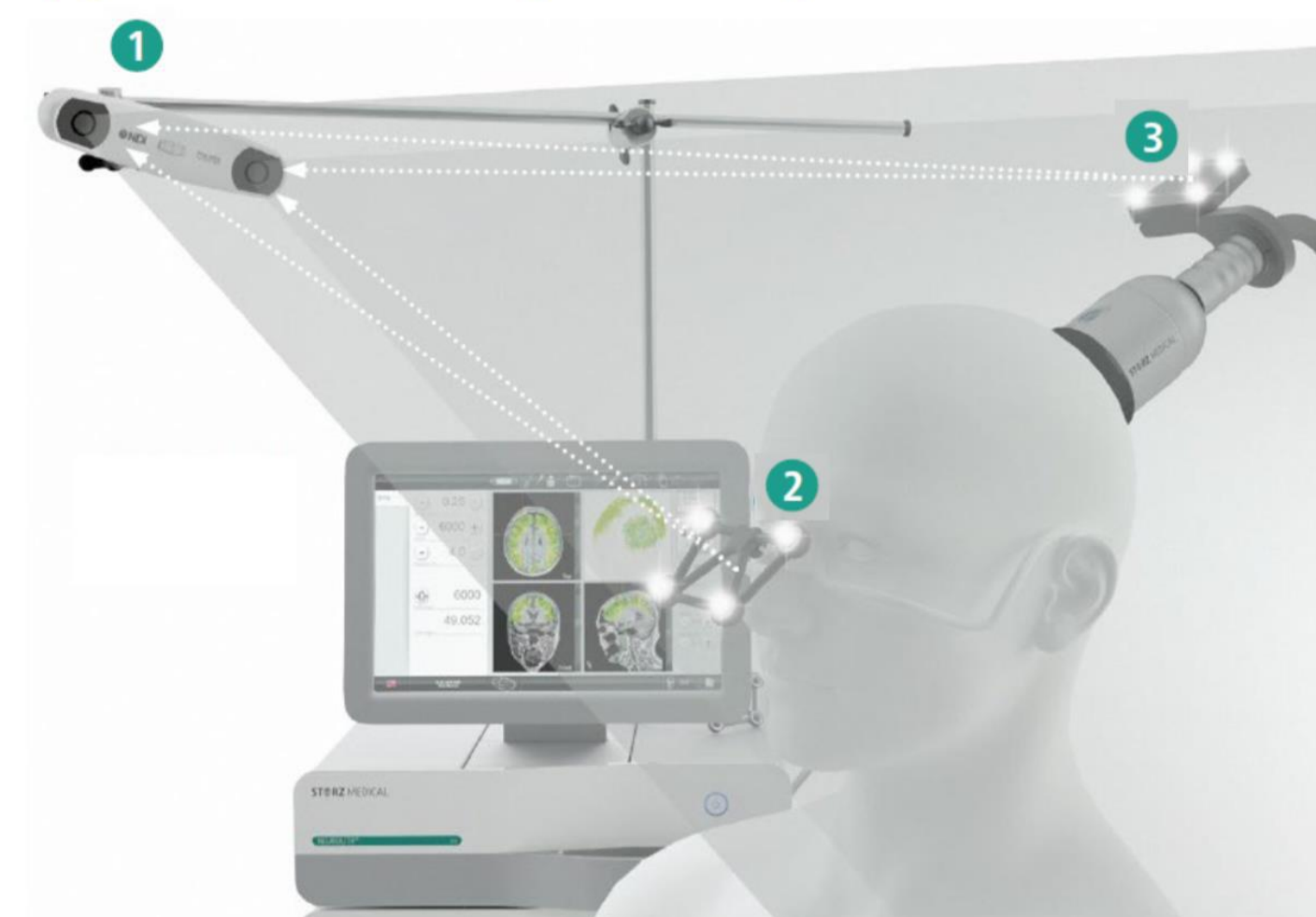


Figure 1.



Results

The treatment was well tolerable with low number of only transient and not severe ADE (From 250 stimulation sessions totally administered: 1.6% drowsiness, 0.8% nausea and headache, and 0.4% jaw pain and earache.)

Short-Term Results

A significant improvement in cognitive scores was detected in all neuropsychological tests:

	n	M	SD	df	t	p	Cohens d
MMST- T0	24	16.17	8.042	23	-2.58	.009*	.53
MMST-Post	24	17.29	7.123				
MoCA – T0	24	11.29	6.517	23	-2.24	.018*	.46
MoCA – Post	24	12.33	6.611				
ADAS – T0	23	28.35	13.217	22	2.58	.009*	.54
ADAS - Post	23	26.04	13.227				

Long Term Results

Long-term data of the mean scores of the group show improvement in cognition after the first treatment cycle, and after 3, 6, and 12 months in every test.

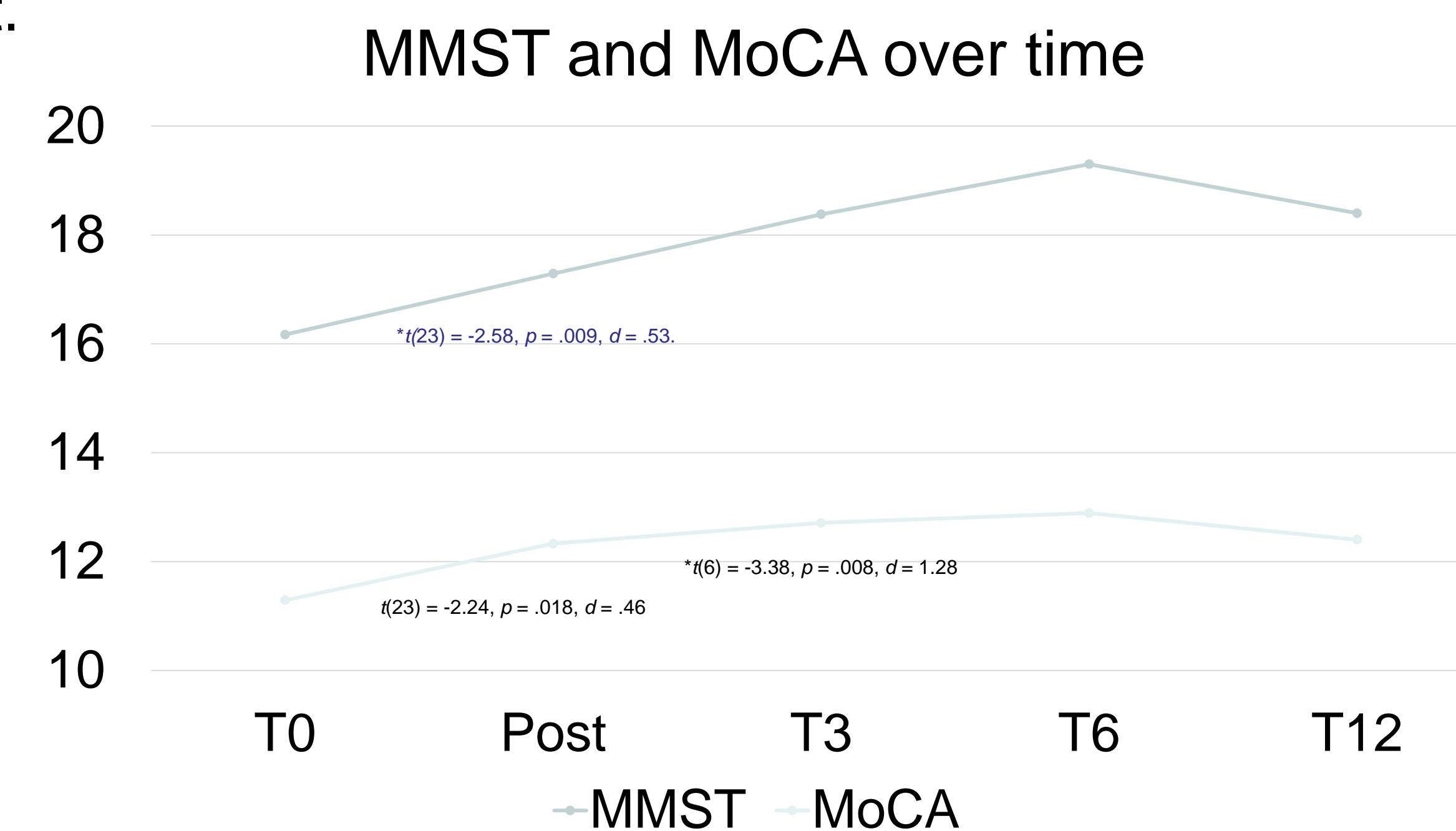


Figure 2. Overall improvement in mean scores over time.

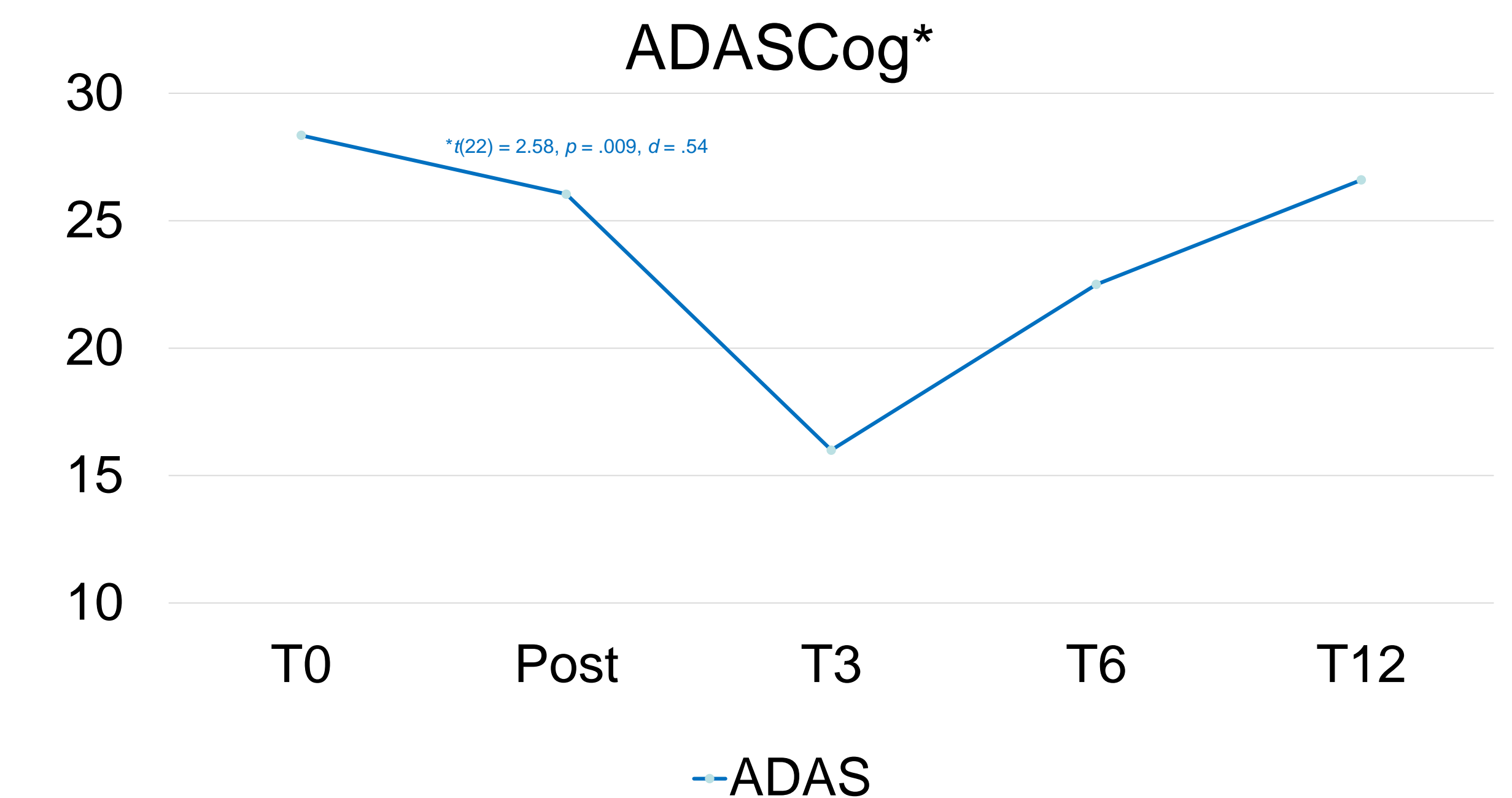


Figure 3. *A lower scores indicates improvement. Mean scores improve after the first treatment cycle and 3 months and then transition back to baseline at 6 and 12 months.

A Pearson correlation was calculated for MMST over time (T0, Post, T3, T6, T12) and revealed no significant change, thus patients show stable performance ($p = 3.21$ with $r = .057$).

Discussion / Conclusion

These pilot results confirm the recently published results with respect to low ADE and extent of cognitive improvement as a short-term effect. These pilot results show that initial improvement of cognitive functions can be maintained up to 1 year. More extensive long term assessments need to be performed in larger groups. Prospective controlled trials need to show the efficacy of this treatment. More data and subgroups need to be analyzed.

References

Cont, C., Stute, N., Galli, A., Schulte, C., Logmin, K., Trenado, C., & Wojtecki, L. (2022). Retrospective real-world pilot data on transcranial pulse stimulation in mild to severe Alzheimer's patients. *Frontiers in neurology*, 13, 948204. <https://doi.org/10.3389/fneur.2022.948204>

Disclosure

LW and CC receive consultancy honoraria and travel payments from Storz Medical.