MHRC 01

The efficacy and safety of Transcranial Pulse Stimulation on young adolescents with Attention-Deficit-Hyperactivity Disorder

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BACKGROUND

Traditional treatment alone might not effectively control the severity of Attention-deficit/Hyperactivity Disorder (ADHD) symptoms. Transcranial pulse stimulation (TPS) is a novel, non-invasive brain stimulation (NIBS) technology which has been proven effective on older adults with Alzheimer's Disease and adults with major depressive disorder. However, there is no study conducted on young adolescents with ADHD.

This is the **first nationwide RCT** evaluating the efficacy and safety of TPS among young adolescents with ADHD in Hong Kong. Clinical Trial Registration: ClinicalTrials.gov, identifier: NCT05422274

METHODS

This study was a double-blind, randomized, sham-controlled trial. A total of 30 subjects aged between 12 to 17, diagnosed with ADHD were recruited from mainstream schools. All subjects were computer randomised into either the TPS group or the sham TPS group on a 1:1 ratio. All subjects undertook fMRI before and after TPS intervention. Six 30-min TPS sessions were administered to subjects in 2 weeks' time on alternate days assessing neural connectivity changes. Baseline measurements and post-stim evaluation of the ADHD symptoms and executive functions were conducted on all participants immediately after TPS, and at 1-month and 3-month, assessing the short-and long-term sustainability of the TPS intervention.

RESULTS

- Male (78%), mean age = 13.1 (SD=1.44)
- **Table 1** showed the group, time, & group x time interaction effects of the outcomes between the TPS group & the sham TPS group.
- Significant interaction effects for ADHD symptoms (SNAP-IV & ADHD RS-IV), executive functions (Reaction time of Stroop test, digit span (DS) – forward), and clinical global impression (CGI) on severity, improvement, and total score were found.

Table 1. The group, time, and group x time interaction effects of the outcomes between the TPS group and the sham TPS group

	Group	Time	Group x Time
	p	*p*	*p*
SNAP-IV (mean)	0.94	<.001***	<.001***
ADHD RS-IV	0.26	<.001***	<.001***
Strooptest1_RT	0.22	0.61	0.03*
Strooptest2_RT	0.11	0.04*	0.02*
Strooptest3_RT	0.04*	0.18	<.001***
DS_Scoreforward	0.60	0.89	0.71
DS_Scorebackward	0.003**	0.75	0.07
DS_Lengthforward	0.71	0.29	<.001***
DS_Lengthbackward	0.03*	0.49	0.06
CGIS	0.82	0.10	0.002**
CGII	0.63	<.001***	<.001***
CGIE	0.41	0.16	0.69
CGI_total	0.33	<.001***	<.001***

Adjusted for age, gender, and drug compliance
***p<.001, **p<.01, *p<.05

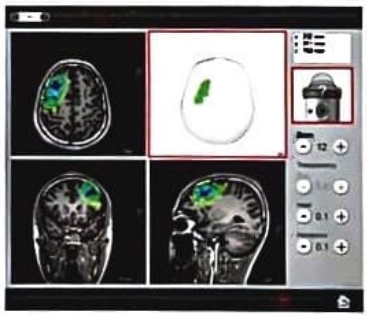

Figure 1. Subject's fMRI (T1 images) after TPS intervention
Treatment region: left dorsolateral prefrontal cortex (DLPFC)

DISCUSSION

- TPS is safe and effective to treat some but not all ADHD symptoms on young adolescents
- Both parents and mental health professionals reported significant changes in cognitive scores in subjects.
- Some parents co-morbid with psychiatric disorders which may affect the ratings towards the subjects in this trial.
- Placebo effects were noticeable in the sham TPS group.

CONCLUSIONS

- To the best of our knowledge, this is the **first** double-blind, RCT evaluating the effects of TPS on ADHD adolescents nationwide.
- TPS is a safe treatment and could be considered as an adjunct treatment for ADHD adolescents in clinical psychiatry.
- Future replication of similar study with multi-site RCT with larger sample & longer follow-up period is warranted.

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Reference: Cheung T, Chau B, Fong KH, Lam JYT, Lo H, Li MH, Li AMMC, Beisteiner R, Lei S, Yee BK and Cheng CPW (2023) Evaluating the efficacy and safety of transcranial pulse stimulation on adolescents with attention deficit hyperactivity disorder: Study protocol of a pilot randomized, double-blind, sham-controlled trial. Front. Neurol. 14:1076086.