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Abstract No

Transcranial pulse stimulation for the treatment of major depressive disorder: A randomized, double-blind, sham-controlled, pilot trial

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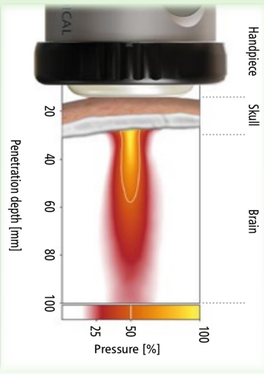
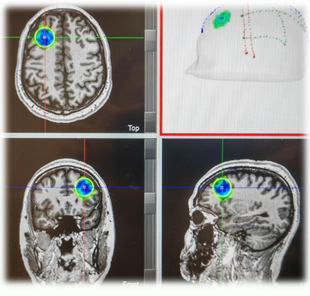


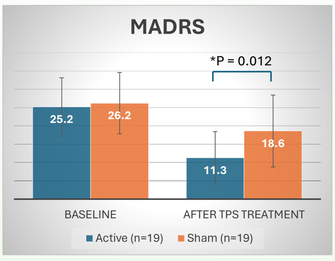
Introduction & Objectives

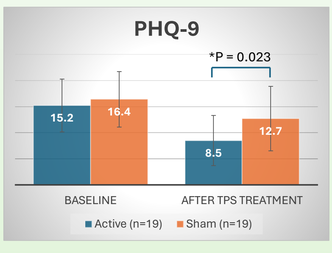
- Major depressive disorder (MDD) is a global disease with a high burden
- **Transcranial pulse stimulation (TPS)** is a novel, non-invasive brain stimulation technique utilizing shockwaves to modulate brain function
- TPS has shown an antidepressant effect in patients with Alzheimer's disease [1] and depression [2]
- Randomized, double-blind, sham-controlled trials are needed to investigate the treatment effect
- Objectives:
  - ✓ To examine the feasibility of conducting a randomized, double-blind, sham-controlled trial of TPS for MDD patients
  - ✓ To investigate the preliminary evidence of the efficacy of TPS on depressive symptoms

Methodology

- Study design: A **randomized, double-blind, sham-controlled pilot trial**
- Participants: 42 patients with MDD were randomized into an **active group (n = 20)** and a **sham group (n = 22)**
- TPS treatment course: 3 sessions/ week, 4 weeks
- TPS parameters:
  - ✓ 1000 pulses/ session
  - ✓ Pulse frequency: 4 Hz
  - ✓ Flux energy: 0.2-0.25 mJ/ mm^2
  - ✓ Target: The left dorsolateral prefrontal cortex (DLPFC), marked by transforming the coordinates (x = -38, y = +44, z = +26 mm) in the MNI space to the individual T1-weighted space
  - ✓ Near-infrared-based real-time neuro-navigation
- Outcome measurements:
  - ✓ The feasibility of the protocol, including recruitment, retention, blinding, and adverse events
  - ✓ The treatment effect on depressive symptoms, as measured by the Montgomery-Asberg Depression Rating Scale (MADRS) and the Patient Health Questionnaire-9 (PHQ-9)







Results

- Recruitment: Of the eligible participants**, 97.7%** were enrolled
- Retention: **90.5%** of the recruited participants completed the protocol
- Integrity of blindness: **47.4%** of the participants correctly guessed the grouping
- **Mild adverse events**: Tingling, pain, numbness, headache, nausea, difficulty concentrating, redness in the skin, and sleep disturbances were reported (18 out of 20 in the active group and 10 out of 22 in the sham group)
- **Promising antidepressant effect** was observed in the active TPS group

Conclusion

- Our randomized, double-blind, sham-controlled pilot TPS trial **is feasible for treating patients with MDD**
- The preliminary results show that **TPS is a promising and effective therapy for patients with MDD**
- In the future, a larger sample size will be included to determine the treatment effect size and to explore the modulation of brain circuits using functional magnetic resonance imaging

References:
[1] Matt E, Dörl G, Beisteiner R. Transcranial pulse stimulation (TPS) improves depression in AD patients on state-of-the-art treatment. *Alzheimers Dement (N Y)*. 2022;8(1):e12245. Published 2022 Feb 10. doi:10.1002/trc2.12245
[2] Cheung T, Li TMH, Ho YS, et al. Effects of Transcranial Pulse Stimulation (TPS) on Adults with Symptoms of Depression-A Pilot Randomized Controlled Trial. *Int J Environ Res Public Health*. 2023;20(3):2333. Published 2023 Jan 28. doi:10.3390/ijerph20032333

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