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Is Seeing Believing? Validity of Modern Sham Coil as a Placebo in Neuromodulation Studies

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Repetitive transcranial magnetic stimulation (rTMS) is a non-invasive brain stimulation technique used to treat conditions involving pathological neurological activity. To establish experimental trial efficacy, a convincing placebo must be used. **PURPOSE:** To determine whether real rTMS could be distinguished from placebo provided by a sophisticated sham coil with identical appearance, sound, and focal scalp electrical stimulation. **METHODS:** Twenty women aged 18-32yr participated (one dropped before receiving sham) after providing informed consent. The leg region of primary motor cortex (M1) was reliably localized on repeated occasions with resting motor thresholds (RMT) determined by Parameter Estimation by Sequential Test (PEST) technique. Participants completed two double-blinded visits (rTMS vs. sham rTMS) in a counterbalanced order with random allocation. Neuromodulation was applied to M1 with intermittent theta burst stimulation (iTBS) at 60% RMT. Afterwards, participants completed a perceived treatment form, asking them to indicate whether they received neuromodulation, and to describe any treatment effects. Responses were analyzed with Monte Carlo Exact tests (CI: 99%, N=10,000) and likelihood ratios (LR). **RESULTS:** iTBS was predicted at chance levels (55%, $\chi^2(1, N = 20) = 0.20, p = 0.83$). Participants were able to identify sham (or were unsure of having received iTBS) 74% of the time ($\chi^2(1, N = 20) = 4.26, p = 0.06$). Participants were 2.09 times more likely to predict neuromodulation after iTBS (LR+), while 0.61 times as likely to receive iTBS after predicting sham (LR-). After iTBS, 42.9% of participants reported treatment effects ($\chi^2(1, N = 20) = 3.20, p = 0.07$); 5.3% reported effects after sham ($\chi^2(1, N = 20) = 15.21, p < 0.00$). While 0.74 times as likely to receive iTBS when reporting no effects (LR-), participants were 5.7 times more likely to have received iTBS when effects were reported. Analysis of written remarks revealed three instances of stimulation percept during iTBS stimulation (e.g. “felt pulses in leg”). **CONCLUSIONS:** Participants are unable to determine whether they received real treatment, but the placebo coil appears less convincing. Future work should consider the use of off-site targets (e.g. visual cortex) as controls in rTMS trials.

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