

Title: Transcranial Infrared Laser Stimulation (TILS) of Prefrontal Cognition in Post-traumatic Stress Disorder (PTSD)

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Study Protocol

Veterans with PTSD are recruited from local community. Potentially qualified veterans will first undergo a diagnostic clinical interview (visit 1). The PTSD symptom scores and other medical information collected in this visit will be reviewed immediately to determine whether eligibility criteria are met. Eligible individuals will be guided to go through an IRB-approved informed consent form that describes the study and the terms of potential participation in the study. If a person chooses to participate, s/he will be scheduled for an fNIRS screening (visit 2). This screening will confirm whether the veteran shows hypoactivations in the prefrontal cortex in the memory retrieval phase – a precondition for study inclusion.

Table 1. Experimental protocol

Aim	Visit	Task
Evaluations & screening	1	Clinical evaluation and consenting
	2	fNIRS scan
Aim 1	3–4	Pre-treatment fNIRS scan Sham or TILS; bbNIRS measurement Post-treatment fNIRS scan
Aim 2	5–9	Pre-treatment fNIRS scan TILS; bbNIRS measurement Post-treatment fNIRS scan

Veterans who pass the initial evaluations and screening will be instructed to receive once weekly TILS treatment at the same light power for seven weeks (visits 3 – 9). In fact, we will administer a sham treatment and a TILS treatment in a randomized sequence during the first two weeks (visits 3 and 4) to determine any acute neurophysiological effects of TILS compared with those induced by sham. Specifically, these effects include: 1) the prefrontal metabolic/CCO changes measured by bbNIRS during the treatment; and 2) the incremental changes of prefrontal activations and scores from three neutral memory tasks, which will be measured by fNIRS before and after the treatment (i.e., post-treatment measures minus pre-treatment measures). Then, statistical analyses will be conducted to determine the acute neurophysiological effects of TILS compared with sham.

After the first two sessions, we will administer another five TILS treatments to the veterans (visits 5 – 9) with fNIRS and bbNIRS measurements taken in each visit. Thus, each veteran will receive a total of six TILS treatments. An iterative statistical analysis procedure will be implemented to determine the least number of TILS sessions that can stably up-regulate prefrontal activity, which will be considered as an optimal TILS dosage.