Hyperbaric Oxygen in Postconcussion Service Members

gas or pressure. Placebo responses are more likely, but unfortunately our study was not designed to evaluate the components of a placebo response such as response expectancy, verbal suggestion, and stimulus conditioning.38 This is an area for further research.

Our trial was not an efficacy trial but rather a pilot study designed to define significant PCS change scores and to determine an effect size to inform sample sizes for potential pivotal trials. The multicenter design improves the generalizability of the findings, but they remain restricted to symptomatic military populations. An additional concern is the absence of validation of a PCS score and defined responsiveness (clinically relevant change scores), but a lack of difference between HBO and sham across all the evaluated domains suggests the findings are not test specific. A confirmatory trial intended to validate the selected outcome measures is under way (clinicaltrials.gov identifier NCT0161194).

Conclusions

Among service members with PCS, HBO showed no benefit over an air sham compression procedure, but symptoms in both groups improved compared with mTBI care without supplemental chamber interventions. This outcome suggests that the observed improvements were not oxygen mediated but may reflect nonspecific improvements related to placebo effects. Taken with results from other concurrent investigations, our study does not support phase 3 trials of HBO for the treatment of PCS at this time.

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