Sleep assessment in a randomized trial of hyperbaric oxygen in U.S. service members with post-concussion symptoms

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Introduction

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Introduction: In this exploratory, double-blind, longitudinal sham-controlled trial of hyperbaric oxygen (HBO_2) for military personnel with mild TBI (mTBI), self-reports and actigraphic measures of sleep-wake disturbances were assessed.

BIMA was conducted at 3 U.S. military sites: Fort Carson, Colorado, Camp LeJeune, North Carolina, and Joint Base Lewis-McChord, Washington.

PRIMARY PUBLICATION REFERENCES:

A randomized trial of hyperbaric oxygen in U.S. service members with post-concussive symptoms. Weaver LK, Wilson SH, Lindblad AS, Churchill S, Deru K, Price R, Williams C, Orrison WW, Walker J, Meehan A, Mirow S and the BIMA Study Team. Undersea Hyperb Med. 2018; 45: 129-156.

Sleep assessments for a mild traumatic brain injury trial in a military population. Walker JM, James NT, Campbell H, Wilson SH, Churchill S, Weaver LK. Undersea Hyperb Med. 2016 Special Edition; 43(5): 549-566.

No conflicts of interest to disclose.

This work is supported by the US Army Medical Research and Materiel Command under Contract No. W81XWH-15-D-0039-0003; ClinicalTrials.gov numbers NCT01611194, NCT01925963. In the conduct of research where humans are the subjects, the investigator(s) adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects).

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Participants randomized (1:1) to 40 sessions (60 minutes each) over 12 weeks:

- Hyperbaric oxygen (1.5 atmospheres absolute, >99% oxygen); or
- Sham sessions (1.2 atmospheres absolute, 21% oxygen)

Sleep assessed at baseline, 13 weeks (after chamber sessions, and 6 months.

Selected sleep measures:

- Pittsburg Sleep Quality Index (PSQI)
- Sleep diary
- Screening for obstructive sleep apnea (OSA) risk (STOP-BANG)
- Restless legs syndrome (RLS) questionnaire
- Cataplexy questionnaire
- Actigraphy

Measures also assessed in healthy volunteers.

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Baseline Findings:

- Sleep quality by self-reports was markedly degraded in the mTBI group at baseline compared to a normative cohort:
  - insomnia 87.3 versus 2.8%
  - OSA risk 70% versus 1.3%
  - Restless legs symptoms 32.4% versus 2.7%
  - all p-values <0.001
- Actigraphy measures did not differentiate between groups.

Follow-up Findings:

- Improvement with HBO_2 compared to sham in 5/8 measures of sleep quality (PSQI) at 13 weeks and 2/8 at 6 months.
- No difference on other measures.

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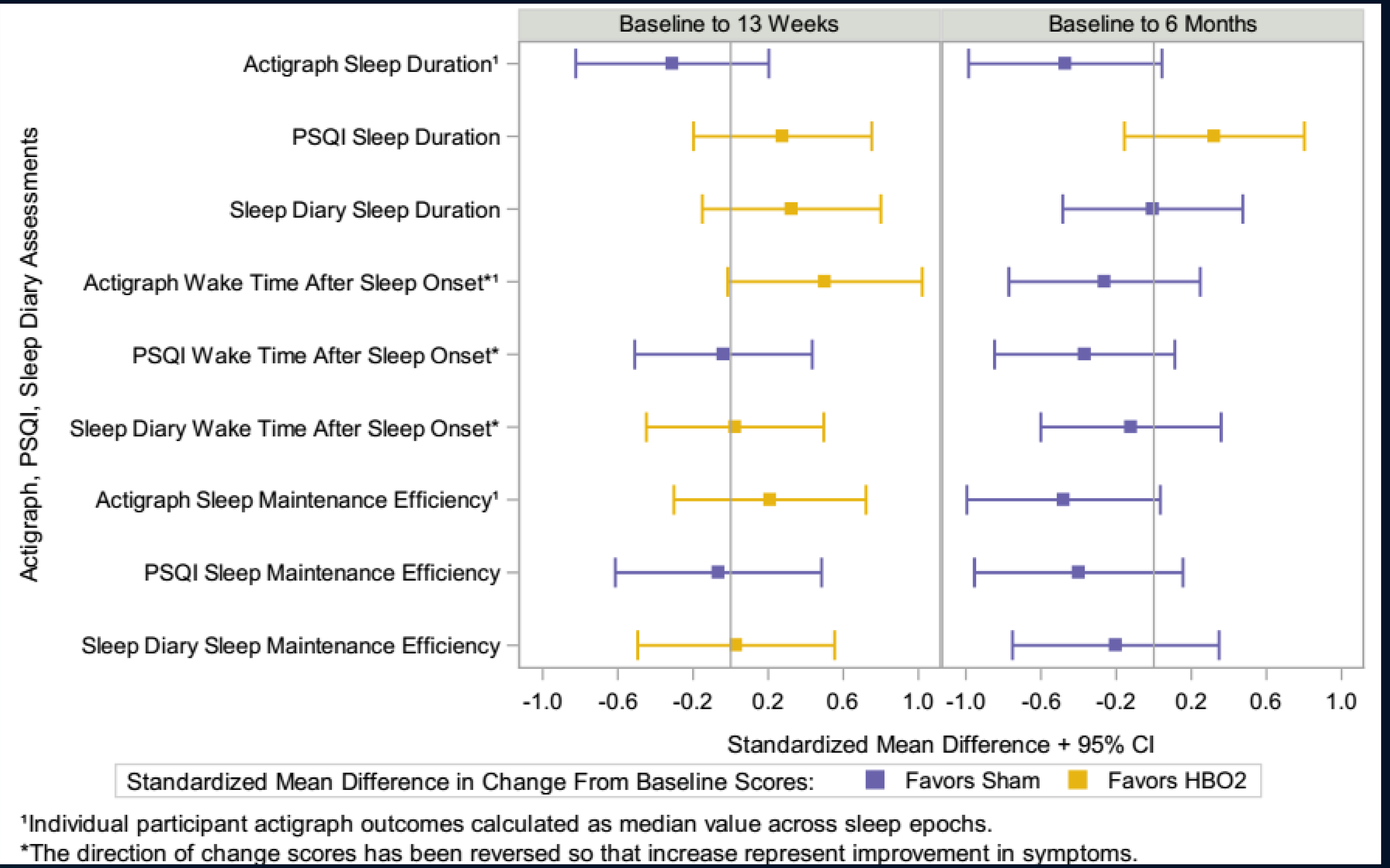

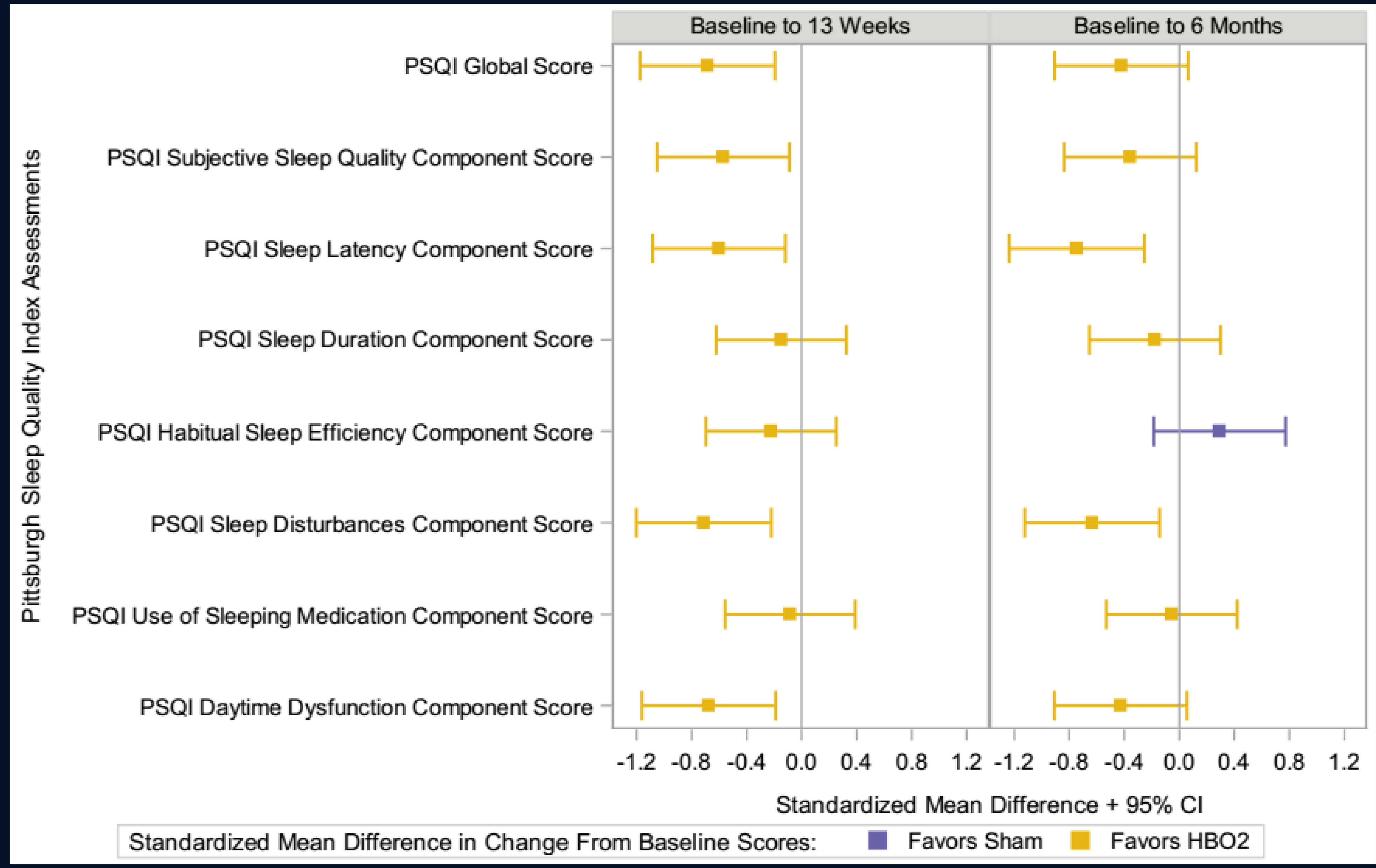

Sleep Assessments Change From Baseline Forest Plot, mTBI Cohort (N=71). The x-axis features a standardized mean difference and corresponding 95% confidence interval for each outcome. The standardized mean difference is taken as difference in change from baseline scores between the two intervention groups divided by a pooled standard deviation.

Conclusions: Perceived sleep quality was markedly disrupted in mTBI military personnel and sleep-wake disturbances were prevalent compared to a normative cohort. HBO_2 relative to sham improved some measures of sleep quality on the PSQI, but other measures of sleep were not significantly different.

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