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Hyperbaric oxygen therapy for primary psychiatric conditions: a protocol for a systematic review and evidence map with narrative synthesis

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ADMINISTRATIVE INFORMATION

Support - No external funding.**Review Stage at time of this submission** - Other - This protocol is registered retrospectively. Prospective registration was not carried out prior to the start of the review because the authors were not familiar with systematic review registration procedures at the time work began.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202650103**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 May 2026 and was last updated on 16 August 2026.

INTRODUCTION

Review question / Objective What is the scope of available human clinical evidence on hyperbaric oxygen therapy for primary psychiatric conditions, and how do study design, HBOT protocol parameters, comparator, outcome measures, efficacy signals, safety reporting, and risk of bias differ across studies?

Background The review now explicitly covers all primary psychiatric disorders, operationalised by DSM-5 diagnostic categories (ICD-10/11 equivalents accepted). In addition to the previously covered trauma- and stressor-related, depressive, anxiety, sleep-wake (insomnia), and substance-related and addictive disorders (including gambling disorder), the scope now explicitly names schizophrenia spectrum and other psychotic disorders, bipolar and related disorders, obsessive-compulsive and related disorders, eating disorders, dissociative disorders, somatic

symptom and related disorders, and personality disorders. Neurodevelopmental disorders (including autism spectrum disorder and ADHD) and neurocognitive disorders are excluded a priori as categories, with rationale; psychiatric symptoms secondary to medical or neurological conditions remain excluded, as do breathing-related and other organic sleep disorders. Diagnostic domains with no eligible studies will be reported explicitly as empty cells in the evidence map.

Rationale A systematic evidence map with narrative synthesis is warranted to establish the current state of the field, distinguish formal HBOT (≥ 2.0 ATA) from subthreshold hyperbaric exposures, and identify diagnostic areas where controlled trials or focused systematic reviews are needed.

This review will also highlight methodological limitations and gaps in safety reporting, which are underaddressed in the current literature.

METHODS

Strategy of data synthesis An outcome-level quantitative dataset (numbers randomised/analysed, numerators/denominators, outcome definitions, effect estimates, measures of uncertainty, time points, missing-data handling, and adverse events) will be provided as supplementary material. Narrative weighting rules will be stated explicitly and reproducibly. The rationale for not conducting meta-analysis will be justified within each diagnostic domain. Safety conclusions will emphasise insufficient safety evidence rather than absence of demonstrated harm; treatment discontinuations and clinically relevant adverse events, including psychiatric adverse events, will be extracted systematically.

Information sources APA PsycInfo is added as a bibliographic information source. PubPsych is retained as a supplementary source but is no longer described as a substitute for APA PsycInfo. MEDLINE/PubMed, Scopus, Web of Science Core Collection, Cochrane CENTRAL, ClinicalTrials.gov and WHO ICTRP are unchanged. Embase remains inaccessible and this will be reported transparently as a limitation.

Eligibility criteria An operational definition of 'primary psychiatric condition' is added: a disorder meeting DSM-IV/DSM-5 or ICD-10/11 criteria (or a validated diagnostic-instrument threshold), with a documented diagnostic-method hierarchy (structured/semi-structured interview > specialist clinical diagnosis > scale threshold only, the latter flagged as lower diagnostic confidence), and a primacy rule requiring that the disorder is not secondary to a medical or neurological condition for which participants were selected. Category-level a priori exclusions: neurodevelopmental disorders (including ASD and ADHD), neurocognitive disorders, and breathing-related/organic sleep disorders. Populations recruited from pain or fatigue clinics remain excluded under the existing medical-condition exclusions. A predefined four-tier evidence classification will be applied: (1) core clinical evidence (primary psychiatric population; UHMS-defined HBOT at or above 203 kPa / 2.0 atm abs); (2) subthreshold-pressure exposures; (3) contextual clinical literature (mixed populations, secondary sleep outcomes, biomarker-only reports); (4) mechanistic/background literature without original human clinical intervention data, which is excluded from the clinical evidence pool and cited only as background.

Data management Title/abstract screening and full-text eligibility assessment will be performed independently by two reviewers, with a predefined disagreement-resolution procedure and reporting of inter-reviewer agreement. Publications will be linked to parent studies/cohorts ('study families'): the number of independent studies or cohorts will be reported separately from the number of reports/publications, and overlapping participant samples will be explicitly identified, with author contact where necessary.

Reporting results / Analysis of the evidence Narrative synthesis and evidence mapping, organised by diagnosis or outcome domain and by study design.

Randomised and non-randomised studies will be summarised and tabulated separately.

Studies using HBOT at ≥ 2.0 ATA will be presented separately from those using subthreshold or mild hyperbaric protocols.

Quantitative meta-analysis is not planned for this protocol. If a subsequent, focused protocol on a specific diagnosis identifies a sufficient number of methodologically comparable studies, meta-analysis will be considered at that stage.

Presentation of the results Tabular summary by diagnosis and study design, accompanied by a narrative evidence map.

Language restriction No language restrictions will be applied during database searching. Final inclusion in the synthesis will require English-language full text.

Country(ies) involved Turkey.

Quality assessment / Risk of bias analysis

Formal result-level risk-of-bias assessments will be conducted and fully documented: RoB 2 for randomised results and ROBINS-I for non-randomised comparative results (with target-trial specification and principal confounding domains), and a design-appropriate descriptive appraisal where neither tool applies. Assessments will be performed by two reviewers, with domain-level judgments, signalling-question responses, and rationales provided in full as supplementary material and summarised at study/result level in the manuscript.

Other relevant information Context and timing: following editorial and peer review at Diving and Hyperbaric Medicine (decision: reject with encouragement to resubmit a substantially reconstructed review), the review is being methodologically reconstructed. The amendments

in this update are registered prospectively, before re-screening for the reconstructed review commences. The original registration was retrospective (May 2026), as transparently reported in the original protocol and manuscript. No changes are made to the registered review question, population, intervention, comparators, or outcomes. Any further deviations will be reported transparently in the final publication together with a protocol-versus-review comparison table.

Keywords hyperbaric oxygen therapy; psychiatric disorders; post-traumatic stress disorder; depression; anxiety; insomnia; sleep disorders; evidence map; systematic review; narrative synthesis.

Dissemination plans Results will be submitted for publication in a peer-reviewed open-access journal in the fields of psychiatry, neuroscience, or evidence synthesis. Findings will also be presented at relevant conferences. The registered protocol will be updated upon completion of the review and publication.

Contributions of each author

Author 1 - Melike Duman Avci - Conceived the review, designed the protocol, drafted the manuscript, and coordinated the review process.

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Author 2 - Ahmet Uğur Avci - Contributed to protocol design, provided clinical and technical expertise on hyperbaric oxygen therapy, and reviewed the manuscript.

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