INPLASY PROTOCOL

Corresponding author:
Cen huijie

1345440752@qq.com

Author Affiliation:
Zhejiang University of Traditional Chinese Medicine.

Support: Mentoring topics.

Review Stage at time of this submission: Risk of bias assessment.

Conflicts of interest:
None declared.

Improvement of Hyperbaric Oxygen Therapy on Cognitive Functions in Patients and animals : A systematic review and meta-analysis

Cen, HJ[1]; Huang, Y[2]; Su, ZY[3]; Wang, MF[4]; Ma, CX[5]; Zhang, JP[6].

Review question / Objective: Review question / Objective: Population: Participants and animals who were definitively diagnosed with cognitive functions were included. No limitations of location, educational background, and gender were imposed. This study will only consider randomized controlled trials (RCTs) of hyperbaric oxygen therapy for the treatment of patients and animals with cognitive functions. However, other studies, such as reviews, case studies, non-controlled studies, and quasi-RCTs, were excluded. Intervention: hyperbaric oxygen therapy Comparison: The control intervention based on the treatment guidelines of cognitive functions, or did not receive any treatment as a blank control. Outcome: Primary outcomes: Results of the cognitive function evaluations. Secondary outcomes: NeuroTrax computerized cognitive testing battery (NeuroTrax Corporation, Bellaire, TX)., computerized cognitive tests (Cambridge cognition, England) , neuropsychological tests included: the Rey-Osterrieth complex figure test (ROCFT), CVLT(California Verbal Learning Test), Wechsler Adult Intelligence Scale–Revised, Montreal cognitive assessment (MoCA) scale, and mini mental state examination (MMSE), eight-arm radial maze , Passive Avoidance Learning Test , Y-Maze Test, Morris water maze, adverse reactions and other outcomes recorded in the article. Study design: This meta-analysis is secondary study and the data were extracted from other people's work.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 June 2022 and was last updated on 01 June 2022 (registration number INPLASY202260005).

INTRODUCTION

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Condition being studied: Cognitive impairment, also known as cognitive impairment, refers to the abnormalities in brain memory, language, reasoning, calculation, emotion, attention, orientation, executive ability, etc., which cause learning and memory disorders and affect the social function and daily quality of life of patients. Patients may have personality, emotional changes, abnormal behavior and other manifestations at the same time.Hyperbaric oxygen therapy (HBOT) utilizes 100% oxygen in an environmental pressure higher than one absolute atmospheres (ATA) to enhance the amount of oxygen dissolved in body's tissues. Repeated intermittent hyperoxic exposures, has been shown to induce physiological effects which normally occur during hypoxia in a hyperoxic environment, including stem cells proliferation and generation of new blood vessels (angiogenesis) . Angiogenesis is induced mainly in brain regions signaling ischemia or metabolic dysfunction . In turn,neovascularization can enhance cerebral blood flow and consequently improve the metabolic

activity . There is growing evidence from clinical studies that HBOT, utilized in a repeated daily sessions protocol, has neurotherapeutic effects which can improve cognitive functions in post-stroke, traumatic brain injury and anoxic brain damaged patients even years after the acute insult.However, there are also relevant clinical reports that hyperbaric oxygen has no effect on the improvement of cognitive function in patients with brain injury. So far, there has been no systematic review and meta-analysis on the improvement of cognitive function in patients and animals by hyperbaric oxygen therapy. This study will evaluate the effectiveness and safety of hyperbaric oxygen therapy on the improvement of cognitive function in patients and animals.

METHODS

Participant or population: Participants and animals who were definitively diagnosed with cognitive functions were included. No limitations of location, educational background, and gender were imposed.

Intervention: Hyperbaric oxygentherapy.

Comparator: The control intervention based on the treatment guidelines of cognitive functions, or did not receive any treatment as a blank control.

Study designs to be included: This study will only include all published randomized controlled trials. The language will be limited to English and there will be no regional restrictions.Case reports, literature reviews retrospective studies, and studies with unbelievable or unavailable data will be excluded.

Eligibility criteria: Participants and animals who were definitively diagnosed with cognitive functions were included. No limitations of location, educational background, and gender were imposed. This study will only consider randomized controlled trials (RCTs) of hyperbaric oxygen therapy for the treatment of patients and animals with cognitive functions. However, other studies, such as

reviews, case studies, non-controlled studies, and quasi-RCT s, were excluded. Intervention: hyperbaric oxygen therapy.

Information sources: This study will use the Cochrane Library, Web of Science, PubMed, EMBASE. There is no definite time limit for the retrieval literature, and the languages are limited to English. We will consider articles published between database initiation and February 2022. The search terms were Cognitive Dysfunction and Hyperbaric Oxygenation.

Main outcome(s): Results of the cognitive function evaluations.

Additional outcome(s): NeuroTrax computerized cognitive testing battery (NeuroTrax Corporation, Bellaire, TX)., computerized cognitive tests (Cambridge cognition, England) , neuropsychological tests included: the Rey-Osterrieth complex figure test (ROCFT), CVLT(California Verbal Learning Test), Wechsler Adult Intelligence Scale–Revised, Montreal cognitive assessment (MoCA) scale, and mini mental state examination (MMSE), eight-arm radial maze , Passive Avoidance Learning Test , Y-Maze Test, Morris water maze, adverse reactions and other outcomes recorded in the article.

Quality assessment / Risk of bias analysis: Two investigators will separately assess the risk of bias of the selected RCT s using the Cochrane risk of bias assessment tool. The evaluation of each study mainly included the following seven aspects: random sequence generation, allocation hiding, blinding of participants and personnel , blinding of outcome assessment, incomplete outcome data, incomplete outcome data, selective outcome reporting, and other biases. Finally, the bias of the study will be rated on three levels: "low", "high", and "ambiguous". These even domains will be separately appraised by two reviews, and discrepancies will be addressed by consulting a third reviewer.

Strategy of data synthesis: We will perform different measurements according to different data types and outcome variables The index types of the data results included in the literature are dichotomous variables and the relative risk(RR) will be used as a statistic and expressed bya95% confidence interval(CI).The weighted mean difference(WMD or standard mean difference (SMD) will be analysed for continuous outcomes.Heterogeneity will be assessed using RevMan 5.4 software.It will measure the $x2$ test and the forest plot and the inconsistencies among the included studies will be quantified using the 12 statistic. When P 50% there is significant heterogeneity among the included studies. The random-effect model will be used to analyze the existence of heterogeneity whereas in the case of no heterogeneity the fixed-effects model will be used for analysis. If the group data cannot be synthesized and subgroup analysis is not available descriptive analysis will be used.

Subgroup analysis: We will investigate the source of heterogeneity using subgroup analysis based on different interventions, controls, and outcomes.

Sensitivity analysis: We will carry out a sensitivity analysis to investigate the robustness and stability of outcome results by removing low methodological quality studies. The main analysis points included the impact of method quality, sample size, and missing data on the study. In this way, we will be able to assess the impact of individual studies on the overall results and determine whether the results are strong.

Country(ies) involved: China.

Keywords: Hyperbaric Oxygenation; Cognitive Dysfunction.

Contributions of each author:
Author 1 - Cen huijie.
Author 2 - Huang yue.
Author 3 - Su ziying.
Author 4 - Wang mengfei.
Author 5 - Ma chenxi.
Author 6 - Zhang jianping.