PROTOCOLOS DE INVESTIGACIÓN - MEDICINA

PHOTOBIOMODULATION IN ALZHEIMER'S DISEASE: A RANDOMIZED CONTROLLED CLINICAL TRIAL PROTOCOL.

Ricardo Lobato Chinarelli (ricardo.chinarelli@gmail.com)

Rosangela Aparecida De Oliveira (Rosangela.oliveira@uni9pro.com.br)

Maria Fernanda Setúbal Destro Rodrigues (maria.destro@uni9pro.com.br)

Rebeca Boltes (rebeca.boltes@uni9.pro.br)

Abstract

Introduction: Alzheimer's Disease (AD) represents a growing public health concern, exacerbated by increased life expectancy and limited therapeutic options. Photobiomodulation therapy (PBM), a non-invasive approach using low-power infrared light applied transcranially, has demonstrated neuroprotective potential in preclinical models. However, robust clinical evidence in humans remains scarce.

Objective: This study aims to evaluate whether transcranial PBM can modify clinical presentation of patients with early-stage AD.

Methods: This is a blind, placebo-controlled, randomized clinical trial to be conducted at a geriatric outpatient clinic facility of university hospital . Fifty patients aged ≥65 years with mild or moderate AD, diagnosed according to standardized clinical and neuropsychological criteria, will be randomly assigned to two groups. The intervention group will receive transcranial PBM thertapy using the Infrallux® device (Cosmedical), which emits ultrashort infrared light through 232 LED diodes, 250 mW/cm² and 1J. The control group will receive sham irradiation with identical procedural cues but without active light emission (equipment turned off). Participants will be assessed at baseline and at post-therapy period of 6 months using validated cognitive and functional scales (MoCA, MMSE, CAMDEX, DRS, CERAD). Statistical analyses will evaluate differences in disease progression between groups using intention-to-treat and per-protocol analyses by ANOVA two-way test comparing baseline and post-treatment moments and groups.

Conclusion: This research protocol explores the therapeutic impact of PBM as an adjuvant treatment for AD. By addressing an unmet clinical need and contributing evidence to an emerging therapeutic modality, this study may provide insights into the development of more effective strategies for managing neurodegenerative diseases.

Palavras-chave: photobiomodulation; alzheimer's disease; dementia; cognitive decline; transcranial stimulation therapy.