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Efficacy and Safety of Electrical Vestibular Stimulation on Adults with Symptoms of Insomnia: A Double-Blind, Randomized, Sham-Controlled Trial

Authors : Teris Cheung, Joyce Yuen Ting Lam, Kwan Hin Fong, Calvin Pak-Wing Cheng, Julie Sittlington, Yu-Tao Xiang, Tim Man Ho Li

Abstract : Insomnia is one of the most common health problems in the general population. Insomnia can be acute, intermittent, and become chronic, often due to comorbidity with other physical and mental health conditions. Although there are conventional pharmaceutical and psychotherapeutic treatments to treat symptoms of insomnia, however; there is no robust and novel randomized controlled trial (RCT) using transdermal neurostimulation on individuals with insomnia symptoms. This gives us the impetus to execute the first nationwide RCT. Aim: To evaluate the efficacy of Electrical Vestibular Stimulation (VeNS) on individuals with insomnia in Hong Kong. Design: This study was a two-armed, double blinded, randomized, sham-controlled trial. Sampling: 60 community-dwelling adults aged 18 and 60 years with moderate insomnia symptoms or above (Insomnia Severity Index > 14) were recruited. All subjects were computerized randomized into either the active VeNS group or the sham VeNS group on a 1:1 ratio. Intervention: All participants received a home-use VeNS device and used 30-min VeNS sessions during five consecutive days across a 4-week period (total treatment hours: 10). Baseline measurements and post-VeNS evaluation of the psychological outcomes, including 1) insomnia severity, 2) sleep quality, and 3) quality of life were investigated. The short-and long-term sustainability of the VeNS intervention was assessed immediately after poststim and at a 1-month and 3-month follow-up period. Data analysis: A mixed GEE model was used to analyze the repeated measures data. Missing data were managed by multiple imputations. The level of significance was set to $p < 0.05$. Significance of the study: This is the first trial to examine the efficacy and safety of VeNS among adults with insomnia symptoms in Hong Kong. Findings that emerged were used to determine whether this VeNS device can be considered a self-help technological device to reduce the severity of insomnia in the community setting and to reduce the global disease burden. Clinical Trial Registration: ClinicalTrials.gov, identifier: NCT04452981.

Keywords : adults, insomnia, neuromodulation, rct, vestibular stimulation
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