07. FREQUENCY RHYTHMIC ELECTRICAL MODULATED SYSTEM (FREMS) AND ITS EFFECT ON THE TREATMENT OF PAINFUL DIABETIC PERIPHERAL NEUROPATHY: A SYSTEMATIC REVIEW AND META-ANALYSIS

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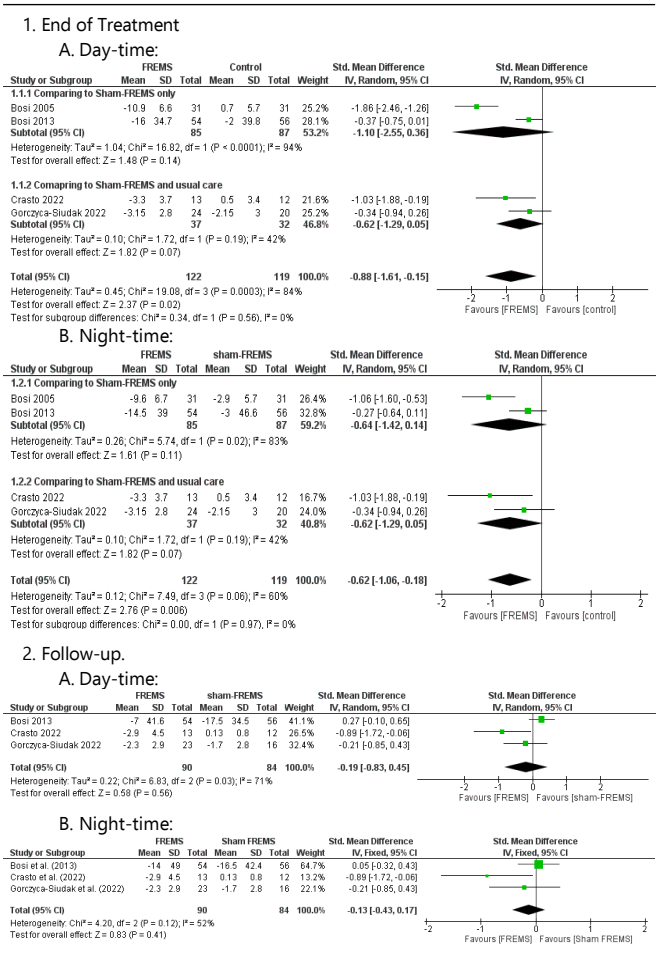
https://www.youtube.com/live/fSpXH-3Xy5w?t=10269s

BACKGROUND: Frequency Rhythmic Electrical Modulated System (FREMS) is an innovative method of transcutaneous non-invasive treatment for neuropathic pain in diabetes mellitus. This study aims to synthesize evidence from published clinical trials on the efficacy and safety of FREMS administration in patients with painful peripheral diabetic neuropathy compared to placebo (sham FREMS) or standard of care. **METHODS**: This systematic review and meta-analysis were conducted following the PRISMA statement guidelines, we searched PubMed, Cochrane Central, Scopus, and Web of Science databases throughout February 2023. Then, we screened the articles for eligibility, extracted the relevant data, and assessed the risk of bias using the Cochrane Collaboration tool. The primary outcome measured was the effect of Frequency Rhythmic Electrical Modulated System (FREMS)on pain perception assessed by Visual analogue scale [VAS] or other pain scores, extracted data from relevant RCTs were analyzed using RevMan software version 5.4.1 for Windows. All steps of this study were prespecified, and the protocol was registered on PROSPERO (CRD42023400884). **RESULTS:** Four RCTs with 210 patients were eligible for the final analysis. For the primary outcome included in the meta-analysis, the mean difference (MD) of change in the (VAS) from baseline to endpoint favoured FREMS over sham-FREMS (comparison with day-time: SMD = -0.45, 95% CI [-0.77 to -0.14], P=0.005; comparison with night-time SMD = -0.41, 95% CI [-0.78 to -0.04], P= 0.03 using a random effect model for both. The efficacy of FREMS decreased gradually, and its statistical significance was lost after the follow-up period (comparison with day-time SMD=0.11, 95% CI [-0.34 to 0.55], P=0.64 using a random effect model; comparison with night-time SMD =-0.13, 95% CI [-0.43 to 0.17], P=0.41 using a fixed effect model. For the secondary outcomes in the systematic review, studies showed no statistically significant difference in Quality of life questionnaires and sensory nerve conduction velocity. Studies on motor nerve conduction velocity, tactile, vibration, and thermal sensation showed conflicting results. All studies reported no major adverse events. **CONCLUSION:** FREMS may offer a drug-free and non-invasive alternative or adjunct modality in pain of peripheral diabetic neuropathy management in patients who do not respond well to treatment or those who cannot tolerate side effects of the usual medications because few side effects were reported after FREMS usage, which in turn makes it safe and well tolerated. In addition to its pivotal role in pain reduction, FREMS may also help in improving sensory functions and NCV in DPN patients. So FREMS should be considered and incorporated into clinical guidelines if further studies continue to support its efficacy and safety.

Figure: Forest Plots of Standardized Mean Difference in VAS Score Changes Comparing FREMS and Control at (1) End of Treatment and (2) Follow-Up: Subgroup Analysis by A. Day-Time and B. Night-Time.



Key Words: Diabetic peripheral neuropathy, Diabetes Mellitus, Frequency Rhythmic Electrical Modulated System.