

Effect of Transcutaneous Electrical Nerve Stimulation on Pain, Function, and Quality of Life in Fibromyalgia: A Double-Blind Randomized Clinical Trial.

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Abstract

BACKGROUND:

Fibromyalgia is a common chronic pain condition that has a significant impact on quality of life and often leads to disability. To date there have been few well controlled trials assessing the utility of non-pharmacological treatment modalities such as transcutaneous electrical stimulation (TENS) in the management of pain and improvement in function in individuals with fibromyalgia. The purpose of this study was to complete a long-term, multi-center study to assess the effects of transcutaneous electrical stimulation in females with fibromyalgia.

METHODSDESIGN:

This is a phase II randomized, double-blind, placebo controlled multi-center clinical trial. 343 participants with fibromyalgia will be recruited for this study and randomly assigned to one of 3 groups, the intervention (TENS), placebo or no treatment. After completing the randomized period, all participants will receive the intervention for one month. The participants will be asked to use TENS at the highest tolerable level for at least 2 hours daily during physical activity. The primary outcome will be pain with movement with secondary outcomes assessing functional abilities, patient reported outcomes and quantitative sensory testing.

CONCLUSIONS:

The results of this study will provide us with some of the first evidence from a large double-blind placebo-controlled trial on the effectiveness of transcutaneous electrical stimulation on pain control and quality of life changes in patients with fibromyalgia.