

Fibromyalgia TENS in Physical Therapy Study (FM-TIPS)

Principal Investigators

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Sponsoring Institution

University of Iowa

Collaborators

- Advanced Physical Therapy and Sports Medicine
- Genesis Healthcare Systems
- Kepros Physical Therapy and Performance
- Rock Valley Physical Therapy
- University of Illinois Chicago

NIH Institute Providing Oversight

[National Institute of Arthritis and Musculoskeletal and Skin Diseases \(NIAMS\)](#)

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ClinicalTrials.gov Identifier

[NCT04683042](#)

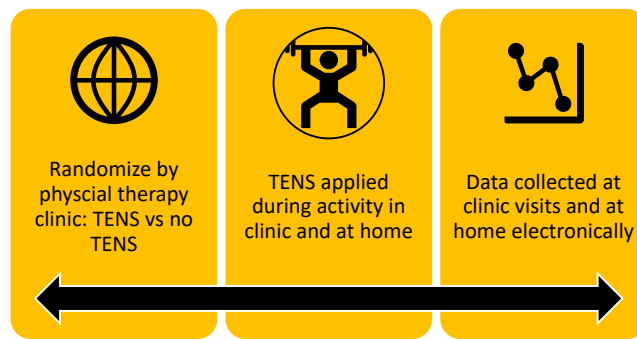
Study Website

[FM-TIPS](#)

ABSTRACT

Fibromyalgia is a chronic pain condition characterized by widespread musculoskeletal pain, tenderness, and stiffness associated with fatigue and sleep disturbance. The goal of reducing opioid use in patients with chronic pain requires that proven nonpharmacologic treatments are applied in clinical practice. A recently completed trial conclusively demonstrated the efficacy of transcutaneous electrical nerve stimulator (TENS) for reducing musculoskeletal pain. While physical therapists are trained in the use of TENS, it is underused in clinical practice. FM-TIPS is an embedded pragmatic trial comparing the effectiveness of physical therapy with or without the addition of TENS for patients with fibromyalgia within physical therapy clinics. The aims of the trial are to demonstrate the feasibility of adding TENS to the treatment of patients with fibromyalgia in a real-world practice setting and to determine if the addition of TENS reduces pain, increases adherence to physical therapy, and allows patients to reach their specific functional goals with less medication use.

FM-TIPS will address the critical need for strategies that implement effective nonpharmacologic treatments for fibromyalgia. Successful completion of this trial will provide generalizable effectiveness data for referring providers, physical therapists, and insurers and will inform future pragmatic trials of nonpharmacologic treatments conducted in physical therapy practices.



WHAT WE'VE LEARNED SO FAR

Challenge	Solution
In order to deliver the FM-TIPS intervention, physical therapy clinicians needed to receive clinical research certification (eg, CITI training), which was a time-consuming step.	The study team worked with the IRB to find options for online training and webinars for clinicians to help streamline the required certification.
The process for collecting patient-reported outcomes (PROs) had to be adjusted to accommodate a transition of the primary outcome to a home test.	The study team met with the Patient-Centered Outcomes Core to find a way to validate the test for movement-evoked pain (the primary outcome) to be conducted online at home by the participant.
Making adjustments due to the onset of the COVID-19 pandemic affected the timing of contracts and the partnership of one healthcare system.	The study team developed a COVID-19 response plan for potential pauses in enrollment or use of telehealth by clinicians.
Incorporating the core domain elements (CDE) for the NIH HEAL Initiative led to changes in data extraction.	The study team collected more PRO measures instead of extracting from the electronic health record.

“We want to make it easy for the clinician to choose nonpharmacologic strategies for treating pain that improve both symptom and function in patients with fibromyalgia.”

PRESENTATIONS & ABSTRACTS

- Presentation: [Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee](#) (2023)
- Living Textbook case study: [Interim Reassessment of Sample Size in Cluster Randomized Trials](#)
- Article (Study Design): [The Fibromyalgia Transcutaneous Electrical Nerve Stimulation in Physical Therapy Study Protocol: A Multisite Embedded Pragmatic Trial](#) (2022)
- [Interview with FM-TIPS PIs](#) (2020)
- Article: [Reduction in movement-evoked pain and fatigue during initial 30-minute TENS treatment predicts TENS responders in women with fibromyalgia](#). (2021)

Access the complete set of [FM-TIPS resources](#).