

FM-TIPS Study Overview

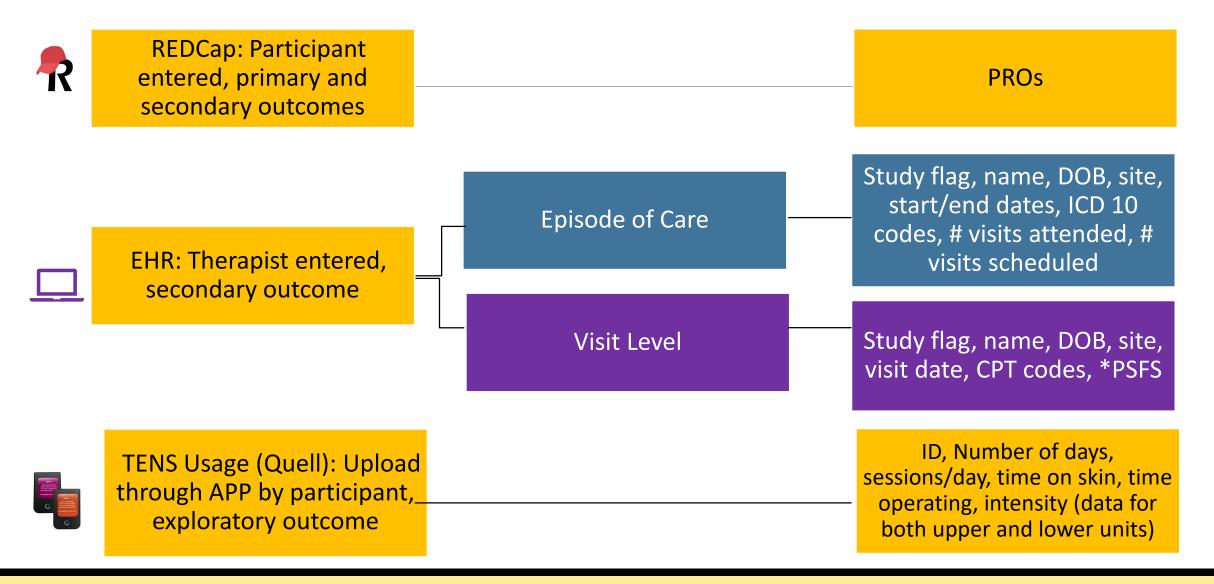
The goal of FM-TIPS is to test the feasibility and effectiveness of adding transcutaneous electrical nerve stimulation (TENS) to standard physical therapy (PT) for individuals with fibromyalgia in a real-world physical therapy setting

- ➤ 25 active physical therapy clinics
 - 10 rural; 15 with ≤ 3 therapists
- > 100+ physical therapists
- > 5 active healthcare systems
- > 11 EHRs



FM-TIPS Data Overview





EHR Data Flow



Data Coordination Center EHR data is requested from Site extracts data from their filters and maps data to clinical site EHR system and uploads to specified format HIPAA-secure shared drive (specific requested data points (excludes data outside date (data is uploaded in various are identified by study team, range of Informed Consent, forms; from Excel files to .jpg and a study participant list is and creates file for upload into images) provided to site) SQL database) **Data Coordination Center** Data is available for analysis and reporting imports to SQL

Challenges

➤ REDCap

- > Study "homework" done online
- > Population older, lower level of education/income
- ➤ Issues with connectivity in ~25% of participants

≻EHR

- > EHR system changes mid-study with access to old systems lost
- Clinic personnel doing the data extraction
 - > Difficult and costly to have EHR vendors run reports
- ➤ Identifying some data elements problematic
 - > Research participants not flagged
 - > Episodes of care not matched to study period
- > Data most reliable when linked to billing (e.g. ICD 10 or CPT Codes)
- ➤ Visit-level data most accessible

➤ Wearable device

- Connectivity TENS to APP, APP to internet
- ➤ APP Requires accurate set-up to match data to participant; data retention limits
- ➤ Need advance planning for what data is required, difficult to go back





Lessons Learned

1

- Do your homework
 - Consult with sites/clinicians, biostatisticians and data managers in the study design phase
 - "Standard" EHRs (e.g., EPIC) and systems with professional data managers much more efficient for data extraction

2

- Sites/clinicians need support
 - Building relationships takes work
 - Focus is patient care, not research
 - Limited time, experience with data

3

- Data managers <u>must be integrated</u> during all phases of the study
 - Need to understand the data from all sources and how it will be collected, extracted, matched, cleaned and integrated