Fibromyalgia TENS in Physical Therapy Study: An Embedded Pragmatic Trial
Barriers and Challenges

- Research Naïve Clinicians
- Technology Ability for Clinicians and Patients
- Recruitment
  - COVID impact on enrollment (PT availability, reduced staff, clinic closing, change in referral patterns, patient availability)
  - FM diagnosis not common reason for referral to PT
  - Changing workflow for PTs Difficult
- Retention
  - Enrollment to completion of Visit 2 (mITT) lower than expected
  - Completion of day 180 at 70%
- Electronic Health Record
  - 6 different systems
  - Clinics have PTs responsible for EHR
  - Clinics switching EHR
Solutions

• Recruitment and Retention
  • Initiated regular contact (phone, e-mail, text) with enrolled subjects after eligibility and enrollment
  • Additional clinics with more intensive training of clinicians
  • Retrained existing clinics in person in the fall
  • Screen all neck and back pain subjects
  • Enrollment incentives, weekly reports, newsletters, on site visits quarterly

• Electronic Health Record
  • Scheduling regular meetings to finalize data pulls, set deadlines
  • Concentrating on data more easily pulled from EHR (no patient-level outcomes)

• Lessons Learned
  • Know where to concentrate efforts
  • Setting expectations for clinics and healthcare system
  • Regular interaction with clinics and patients critical to maintain engagement
  • Being available to answer clinician and patient questions