



FM-TIPS

*Fibromyalgia TENS In
Physical Therapy Study*

IOWA

VANDERBILT  UNIVERSITY
MEDICAL CENTER

Community Engagement Methods for Recruitment



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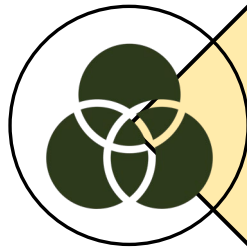
Heather Schacht Reisinger, PhD

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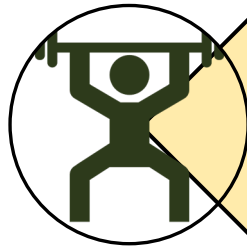


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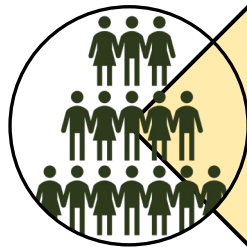
*Fibromyalgia TENS In
Physical Therapy Study*



cluster-randomized
pragmatic trial



routine PT with
or without TENS



enroll ~450 people
with fibromyalgia

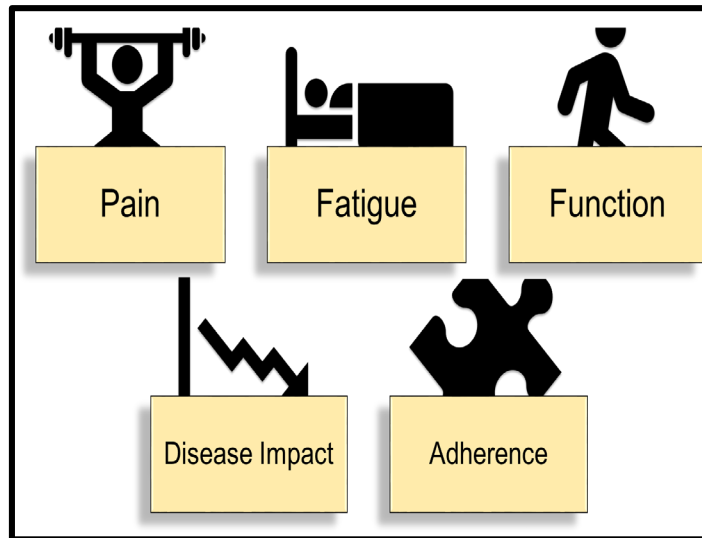
The goal of the study is to test the feasibility and effectiveness of adding TENS to standard physical therapy (PT) care in a real-world physical therapy setting

Study Outcomes



FM-TIPS

*Fibromyalgia TENS In
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Primary Outcome

- Change in Movement Pain (Baseline to 60 days)

Secondary Outcomes

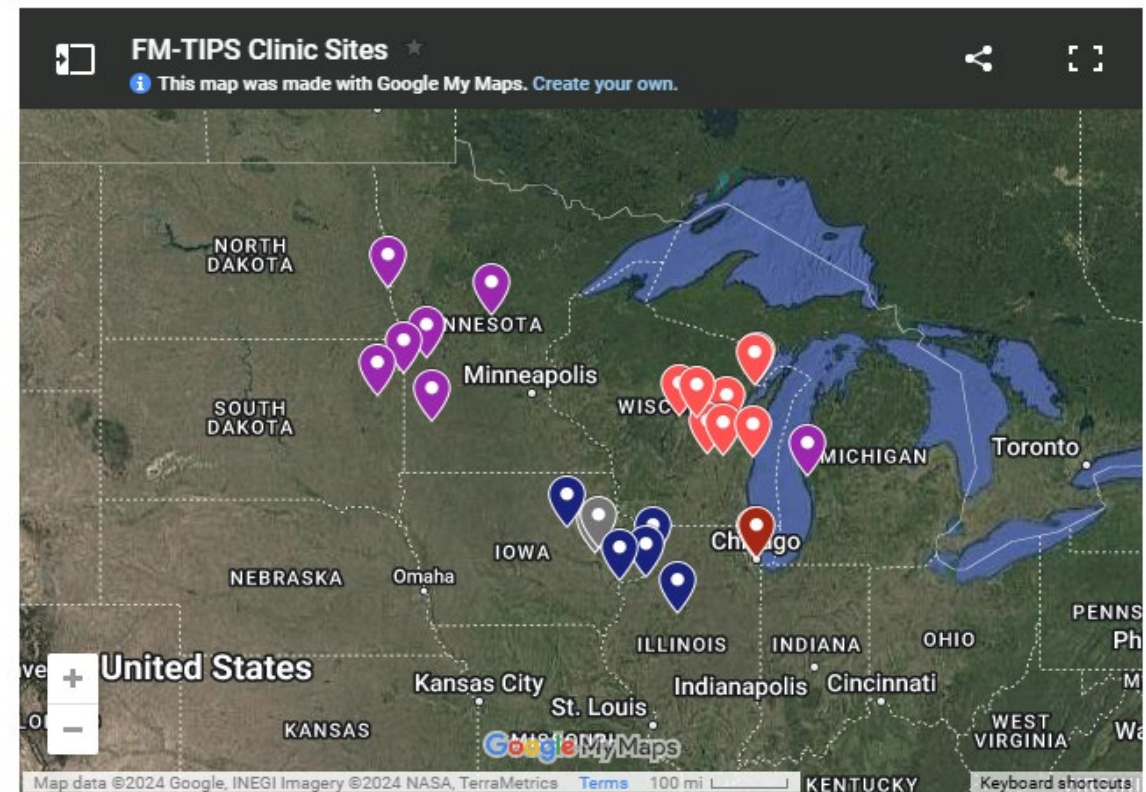
- Pain interference
- FM disease activity
- Resting pain and fatigue
- Movement-evoked fatigue
- Multidimensional fatigue assessment
- Physical activity
- Patient global impression of change

Additional Outcomes

- Patient-Specific Functional Scale
- HEAL Initiative outcomes

Physical Therapy Clinics and Communities

- 7 states in the Midwest
- 6 healthcare systems
- 25 physical therapy clinics
 - 10 rural clinics
 - 15 urban Clinics
- 100+ physical therapists



Healthcare System and PT Clinic Selection

Healthcare System

- Ability to do EHR extraction
- Complete paperwork for the grant
- Provide a contact for each clinic
- Ability for clinics to complete human subjects' protection and study training
- Allow for periodic meetings with study team

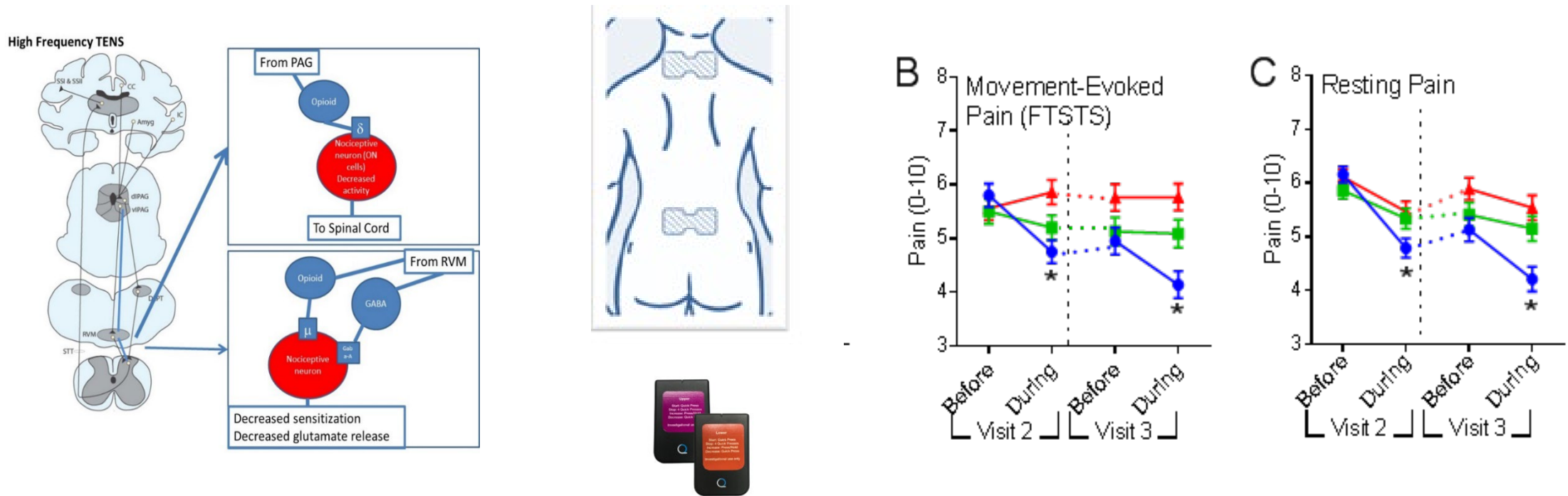
PT Clinic Selection Criteria

- PT clinic had 50 or more patients in the last year with chronic pain
- PT healthcare systems and clinics could be in private practice (n=5) or at an academic medical center (n=1)
- PT clinics were interested in clinical research
- Initial clinic recruitment goal of 25 participants by the end of the study (~1 per month)

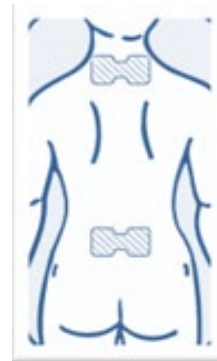
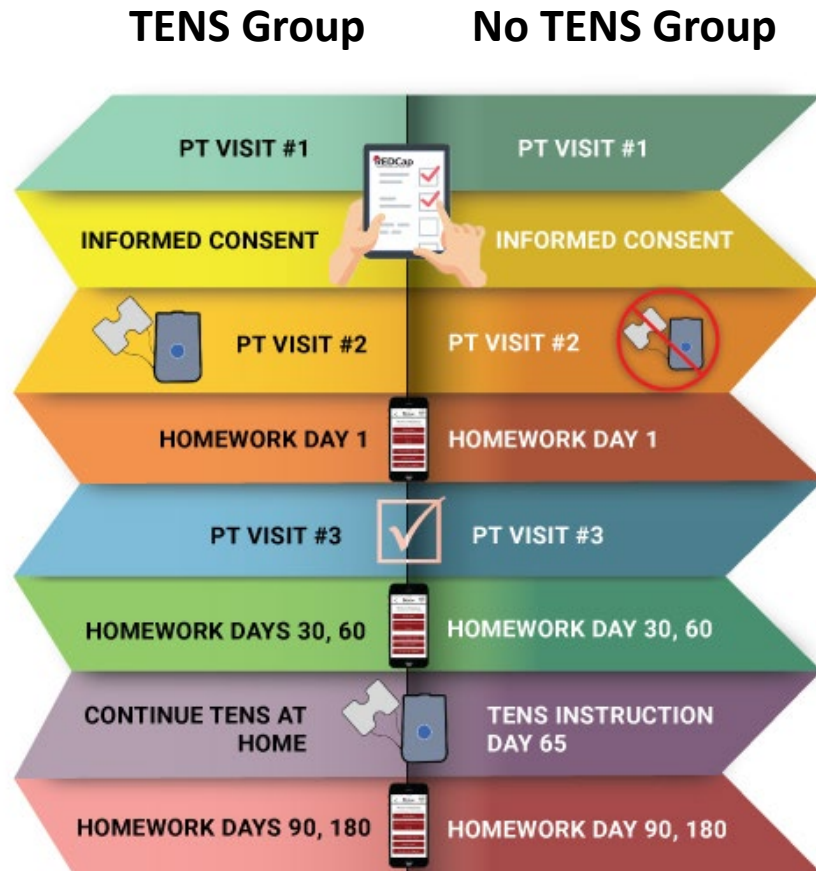


Evidence for Transcutaneous Electrical Nerve Stimulation (TENS Evidence)

Parameters are important for success – intensity, frequency, duration, and activity



Participant Involvement



- Attend physical therapy (at their own cost)
- 6-month involvement in the study
- Homework done at home through REDCap; log into TENS app once a week.
- Receive 2 free TENS units; wear TENS up to 2 hours a day
- Payment up to \$200 if all homework completed

How did we define screening, enrollment and mITT?

Screening

Passing REDCap screening on clinic iPad



Enrollment

eConsent and 2nd signature by study team



Modified intention-to-treat (mITT)

Completion of resting pain rating on REDCap before at beginning of homework day 1



FM-TIPS Clinical Team

Study Team Representatives (STRs)



- Communication
 - Health care systems and contacts
 - Clinicians
 - Providers
 - Training
 - Updates and Meetings
 - Participant assistance
- Posting information
- Provider Contacts

Participant Communication Team



- Study Inquiries
- Communication with Participants
 - Answer Questions
 - Homework Reminders
 - Equipment Ordering
- Communication with Clinicians

Community Engagement Coordinators



- Communication
 - STRs, Clinics and Clinicians
 - Physician Liaisons
- Provider Information and contacts
- Community Organizations
- Posting information
- Media contacts and information
- Documentation and Assessment

FM-TIPS Study Timeline



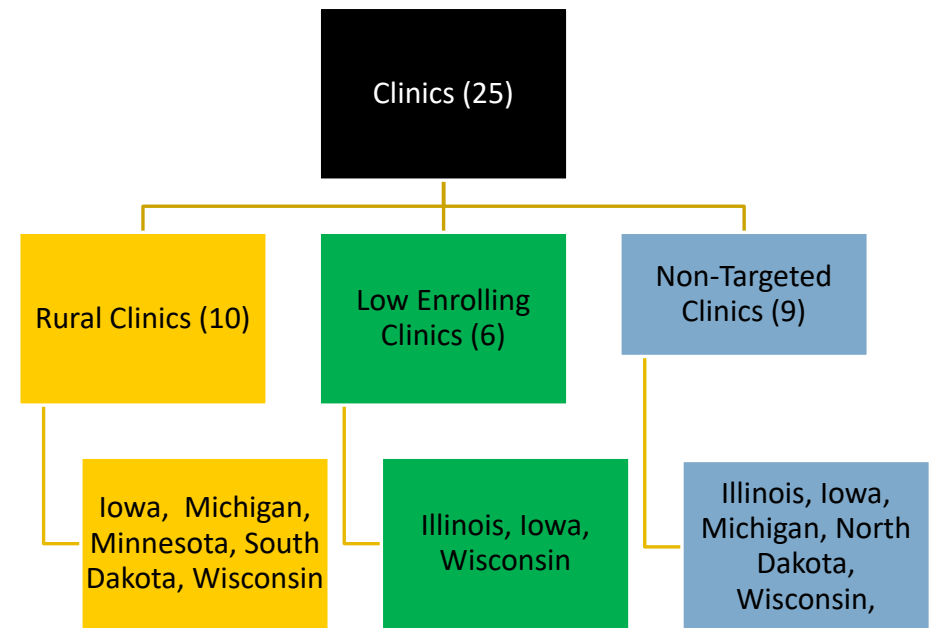
Community Engagement (CE)



Community Engagement Coordinators activities occurred between June 2023 and August 2024



The 25 active PT clinics were categorized in 3 groups based on RUCA codes (4-10) for rural and others based on enrollment over the last 12 months



FM-TIPS PT Clinic and Community Relationships



Community Engagement Planning

- Deep dive into clinic communities
- Input and feedback from clinicians
- Development of an individualized clinic and community plan
- Plan for 3 months at a time for each clinic
 - Document Review and summarize monthly
 - Modify and adapt as needed
 - Plan future activities and travel plans
- Weekly meetings




Community Engagement Process




Community Research

- Demographics
- Employers




Community Research

- Community Organizations
- Fitness Centers
- Extension Services




Medical Providers

- Primary healthcare providers Specialty healthcare providers
- Additional providers such as Dentists, Massage Therapists, etc.



Interviews

- Study Team Representatives
- Clinicians



Additional Community Resources

- Libraries
- Churches
- Parish Nurses

Community Engagement Strategies



Flyers

- Patient/Participant Focus
- Lead potential participants to study website or clinic
- Different than flyers posted in clinics
- Requires posting & reposting



Direct Mail

- Direct mail initially sent to 10 rural communities
- Expanded to low enrolling clinics
- Based on age, population, and distance to PT clinic



Social Media

- Development of Facebook page
- Attempted Facebook live events with limited success
- Drive interested people to study website
- Newspapers, TV, Radio



Social Media Ads

- Facebook Ads for the study in rural communities
- Facebook media for clinics to share on clinic Facebook pages or clinic media in clinics
- Google Ads were not successful



Community Events

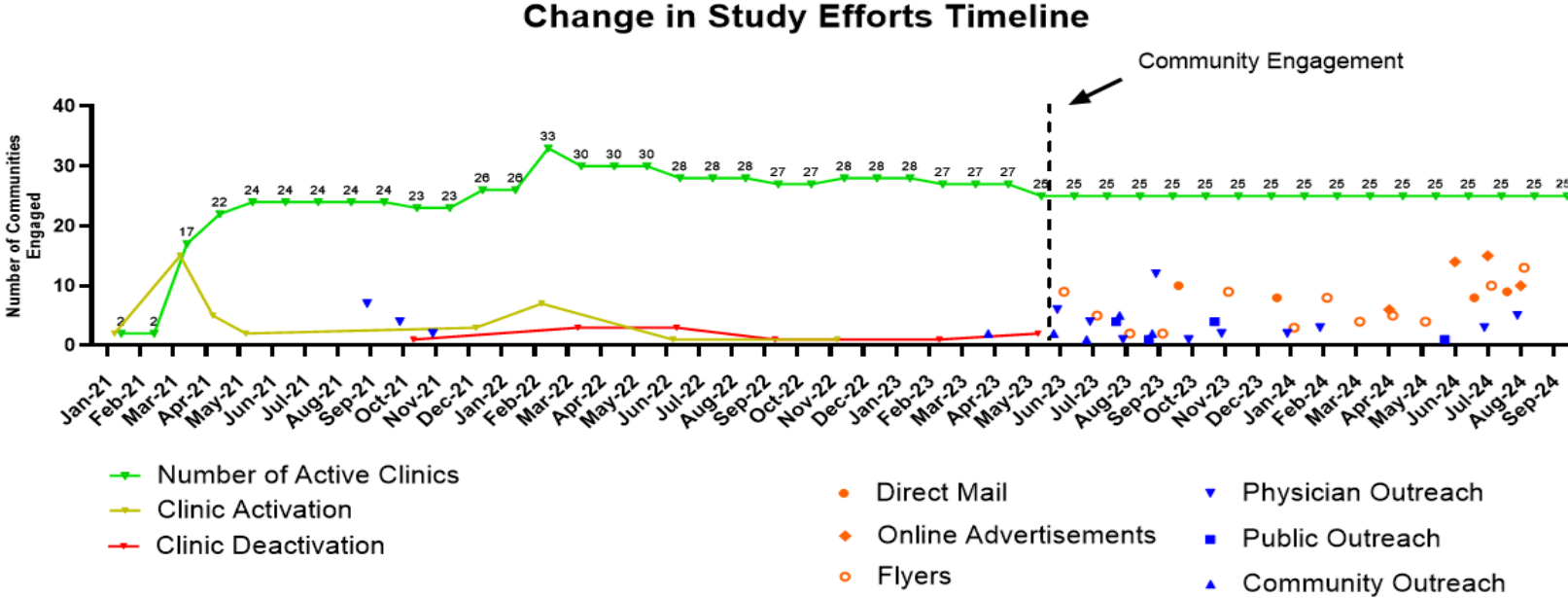
- Education at Community Events
- Exercise
- Chronic pain
- Fibromyalgia
- TENS



Provider Materials

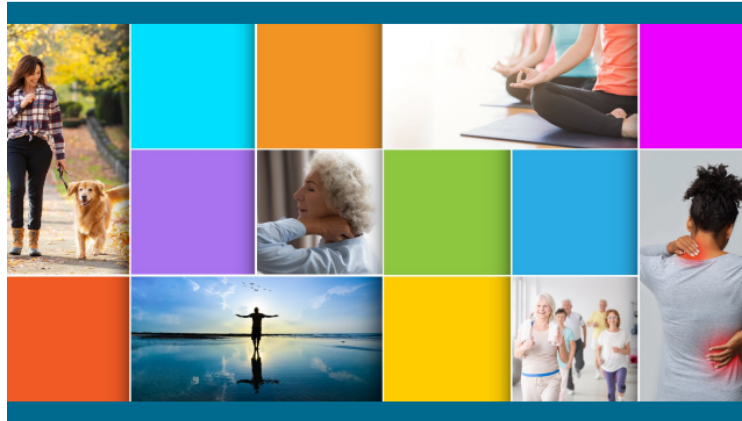
- Flyers for the clinic
- Letters to Providers
- Packets with FM & TENS research

Community Engagement Efforts



Flyers

Do you have Fibromyalgia?
Are you interested in a research study?



- We are looking to see if TENS combined with Physical Therapy helps reduce pain for people with Fibromyalgia.
- Participation in the study involves visits to a local Physical Therapy Clinic and doing surveys at home. You will be responsible for payment for the physical therapy services.
- You will be paid for your time and effort and receive materials and 2 TENS units free of charge.

This research study is being conducted in local PT clinics with support from the University of Iowa and Vanderbilt University Medical Center.

Contact the research team about enrolling

fmtips-studyteam@uiowa.edu



www.fmtips.org 319-467-4203



SWITCH OUT
CLINIC LOGOS



Let's Do Something About Fibromyalgia And Chronic Pain

YOU CAN HELP US LEARN ABOUT CHRONIC PAIN AND
FIBROMYALGIA BY BEING IN A RESEARCH STUDY

[CLINIC NAME] Physical Therapy in [CLINIC LOCATION] is dedicated to helping you decrease chronic pain and increase activity.

You may be eligible if you have
fibromyalgia or chronic pain

HERE'S WHAT THE STUDY INVOLVES

- Go to physical therapy at [CLINIC NAME] Physical Therapy *You'll be responsible for payment of PT services
- Complete 5-6 surveys from home over 6 months
- Receive 2 tens units free of charge
- Payment for you time and effort



CONTACT THE RESEARCH TEAM
ABOUT GETTING INVOLVED

fmtips-studyteam@uiowa.edu
www.fmtips.org
319-467-4203



Contact
Us Today

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Direct Mail Postcard




DO YOU HAVE FIBROMYALGIA?


[Clinic name] is doing a research study with the University of Iowa and Vanderbilt University Medical Center

We are looking to see if TENS combined with Physical Therapy helps reduce pain. You may be eligible if you have fibromyalgia and are 18 years or older.

Join the Fibromyalgia TENS in Physical Therapy Study TODAY!


 **FM-TIPS**
Fibromyalgia TENS in Physical Therapy Study

 **UNIVERSITY OF IOWA**
HEALTH CARE

 **VANDERBILT UNIVERSITY**
MEDICAL CENTER

SWITCH OUT CLINIC LOGOS [street name] [city, state zip]
[phone number]

www.FMTIPS.org
fmtips-studyteam@uiowa.edu
319.467.4203



FM-TIPS
500 Newton Road, 1-252 MEB
University of Iowa
Iowa City, IA 52242-1089

What do I need to do?

- Visit [Clinic Name]
- Complete online surveys at home
- Wear a TENS unit for 2 hours a day

You will be paid for your time (up to \$200) and 2 free TENS units.

Contact study team at
fmtips-studyteam@uiowa.edu
319.467.4203

Fibromyalgia TENS in Physical Therapy Study
1m · 🌐

Many people with Fibromyalgia experience headaches that can have a significant impact on their quality of life. Our Partners at Rock Valley Physical Therapy share how physical therapy could help:

#LetsDoSomethingAboutFibromyalgiaPain #fmtips



ROCKVALLEYPT.COM
Physical Therapy for Headaches: Does it Work? | Rock Valley


Fibromyalgia TENS in Physical Therapy Study allows profiles and Pages it mentions to comment on this post.

Write a comment...

Fibromyalgia TENS in Physical Therapy Study
1m · 🌐

Playing pickleball can be a fun way to get moving this spring – our partners at [Keptos Physical Therapy](#) share tips on playing safely.

#LetsDoSomethingAboutFibromyalgiaPain #fmtips



KEPROSPT.COM
Pickleball injury got you in a pickle? — Keptos Physical Therapy & Performance

Fibromyalgia TENS in Physical Therapy Study allows profiles and Pages it mentions to comment on this post.

Write a comment...

Fibromyalgia TENS in Physical Therapy Study
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Physical therapists can use many different technologies to develop a pain management plan that works best for your individual needs. Read more about digital tools physical therapists use on [ChoosePT's](#) website:

#LetsDoSomethingAboutFibromyalgiaPain #fmtips



CHOOSEPT.COM
Health Tips | What Is Digital Health in Physical Therapy
Digital health is the fusion of medical knowledge with technology. Learn how a physical therap...

Fibromyalgia TENS in Physical Therapy Study allows profiles and Pages it mentions to comment on this post.

Write a comment...

Examples of social media ads – clinic specific



Community Engagement (CE) Documentation

- CE Coordinator Field Notes
- Study Inquiry log
- Participant Communication Log
- Community Engagement Notes in Redcap
- Data:
 - Weekly reports
 - Diversity reports - rurality and ethnicity
 - Clinic Stoplight report

Community Engagement Tracking



Data Collection Instrument	Status
Clinic Name	<input type="radio"/>
Healthcare System	<input type="radio"/>
Clinics	<input type="radio"/>
Clinic Active or Inactive	<input type="radio"/>
Clinicians	<input type="radio"/>
Clinic Visits	<input type="radio"/>
Clinic Communication	<input type="radio"/>
FM-TIPS Study Communication	<input type="radio"/>
Clinic Screening and Enrollment	<input type="radio"/>
Community Information	<input type="radio"/>
Community Partners and Events	<input type="radio"/>
Referring Provider Offices	<input type="radio"/>
Referring Providers	<input type="radio"/>
Provider Contact Log	<input type="radio"/>
Community Contact Log	<input type="radio"/>
Community Events Log	<input type="radio"/>
Provider Mailing Log	<input type="radio"/>
Continuing Education	<input type="radio"/>
Continuing Education - Clinician	<input type="radio"/>

Field Notes

- Clinic, Location
- Activities
- Community
- Observations
- Relevant notes



CE Monthly Summaries

- Clinic, System
- What we did
 - Providers
 - Clinics
 - Community organizations
 - Events
- How did it work?
- Plan for next month
- In the works/Upcoming



How Did You Hear About FM-TIPS?

Participant Screening

Tell us about how you heard about the study. Select all that apply in the list below.

- I talked to someone
- I saw a flyer
- I saw a Facebook post
- I read or heard about it through a postcard, website, or another media source

Who did you talk to? Select all that apply.

- My physical therapist
- My doctor or nurse
- A friend or relative
- Someone at an information session
- A parish nurse

Where did you see the flyer? Select all that apply.

- I saw a flyer at the PT Clinic
- I saw a flyer at the doctor's office
- I saw a flyer posted in my community

Where did you see the Facebook post? Select all that apply.

- On the PT Clinic Facebook page
- On a community Facebook page

Where did you read or hear about it? Select all that apply.

- From a postcard in the mail
- In a newspaper or newsletter
- On the radio or TV
- On a website about the study

Study Inquiry Log (Questions about the study)

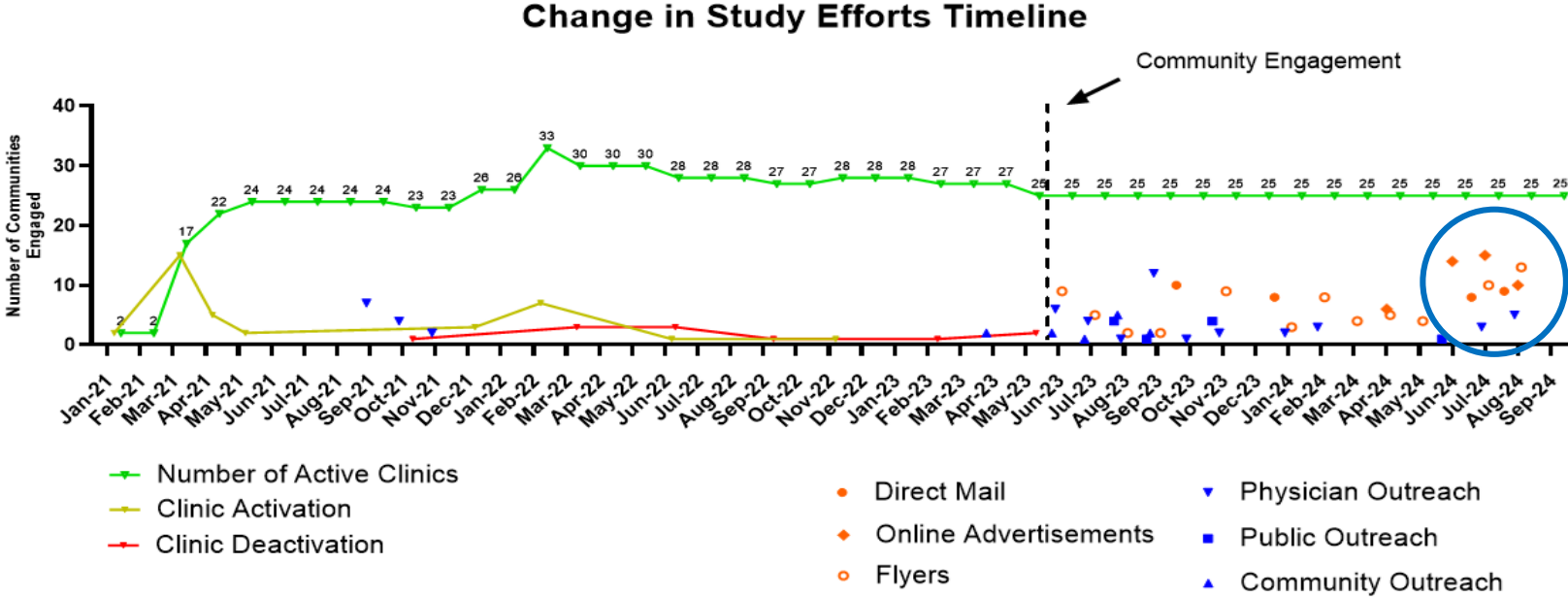
- Individual contact information
- How did you hear about the study?
- Follow up
- Comments

Communication Log (Enrolled participants)

- Participant number
- Clinic
- Date
- Study team member
- Who contacted us
- Timepoint
- Problem
- Reason for communication
- Urgent vs Non-urgent

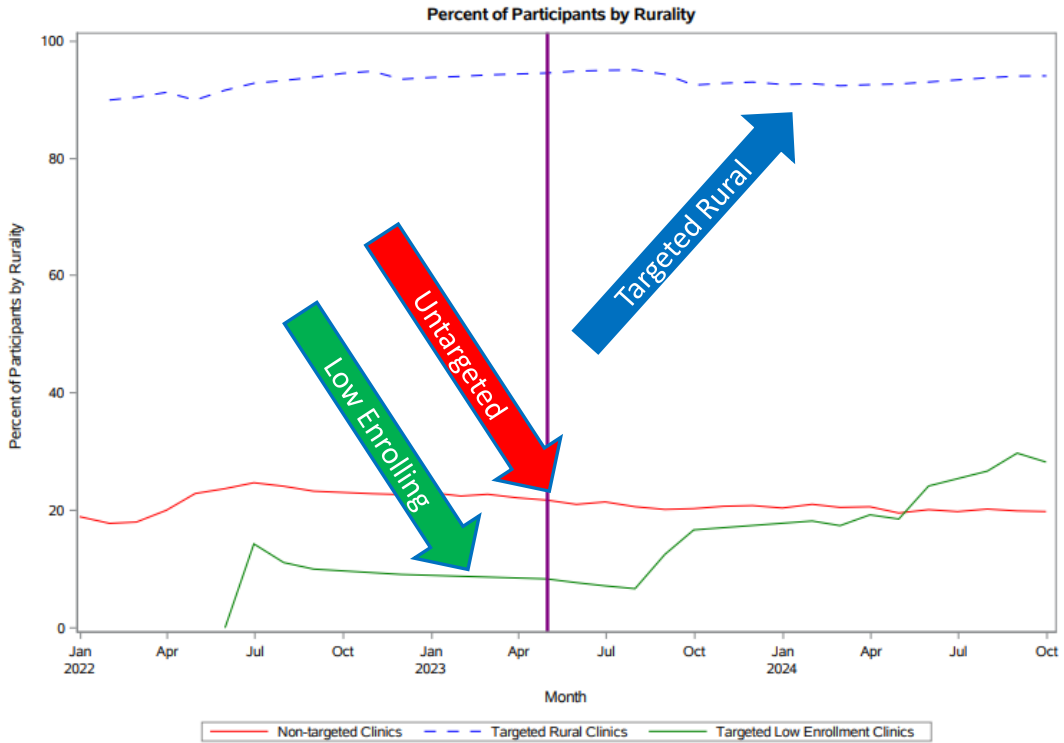


Community Engagement Efforts



mITT and rurality of participants by clinic target

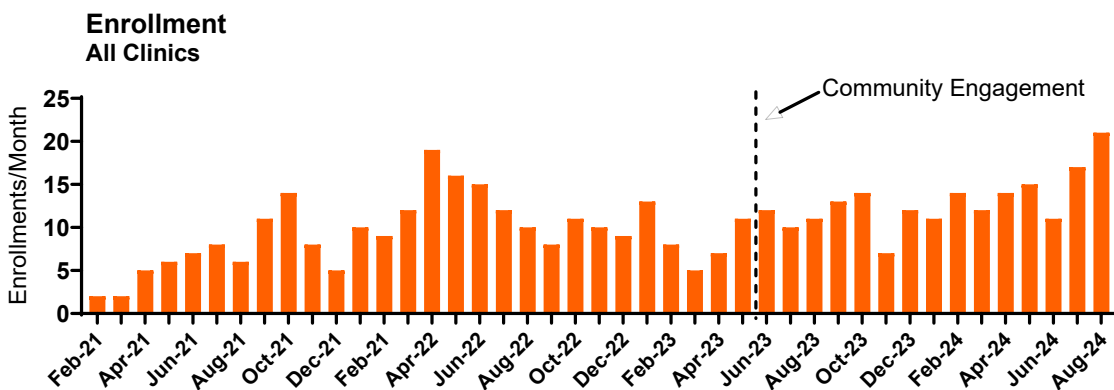
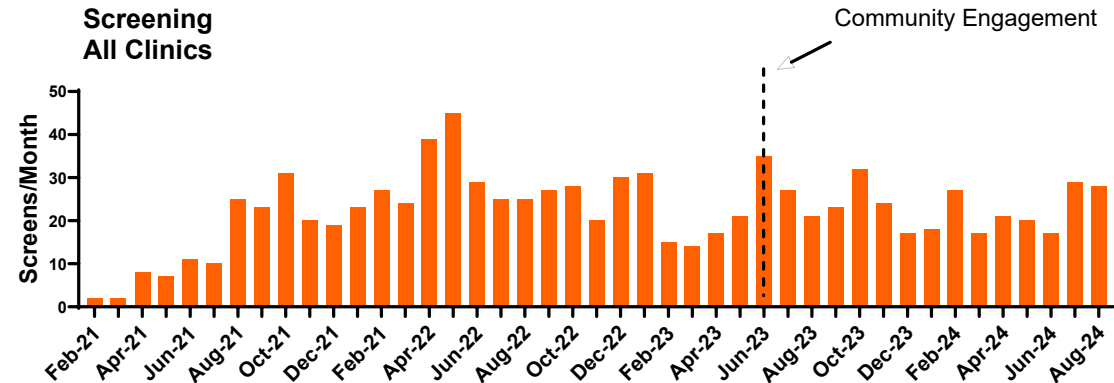
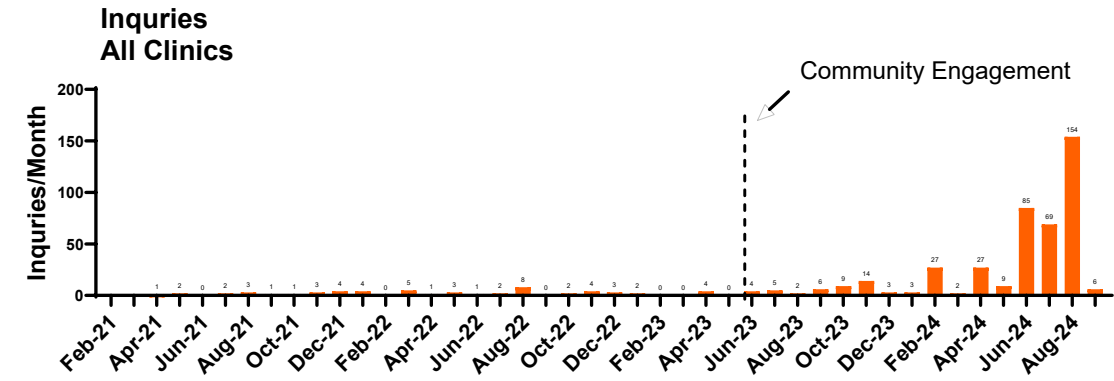
Percentage mITT by Rurality



All Clinics

Pre and Post Community Engagement (CE)

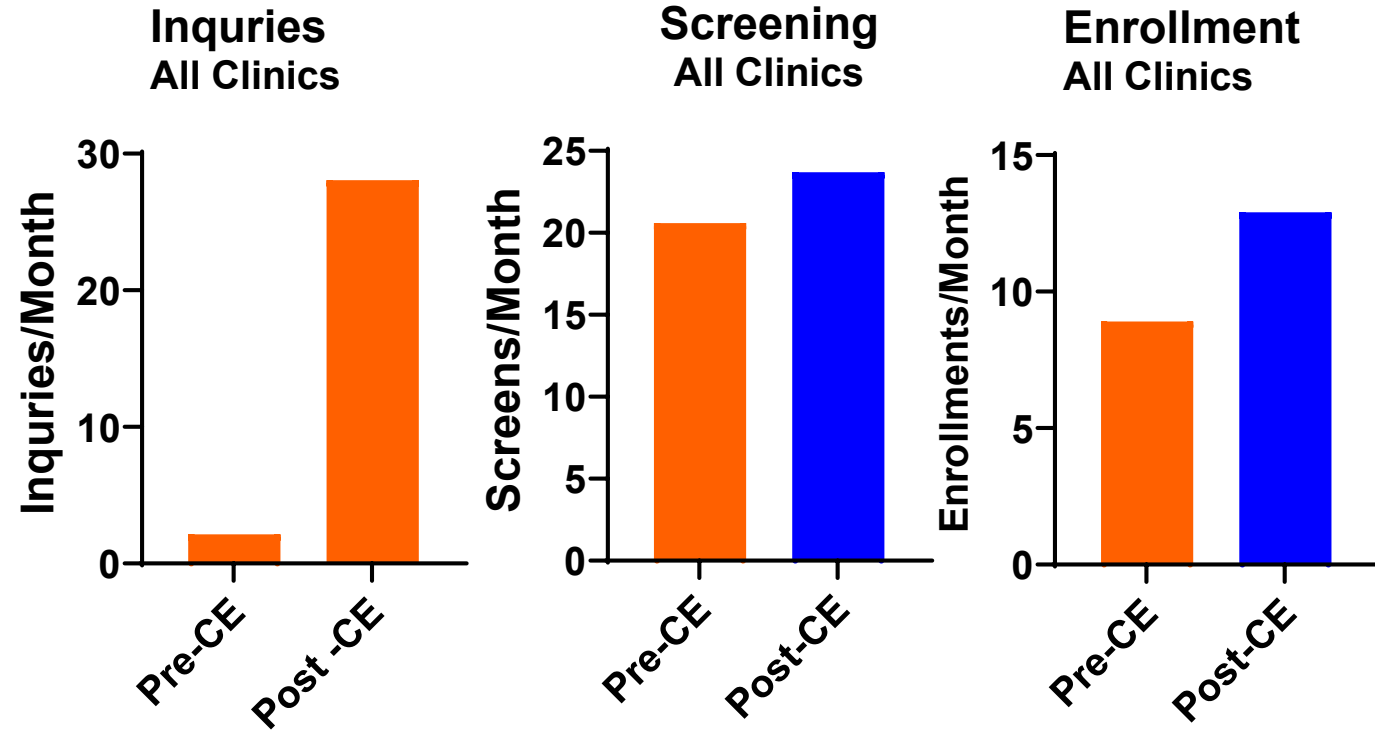
- Inquiries
- Screening
- Enrollment



All Clinics

Pre and Post Community Engagement (CE)

Inquiries
Screening
Enrollment

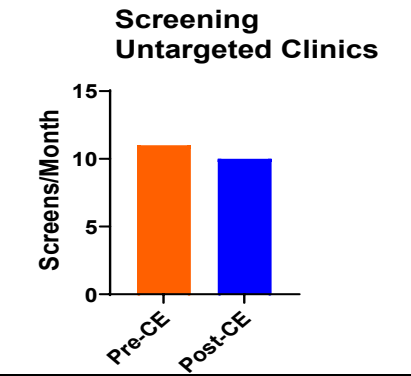
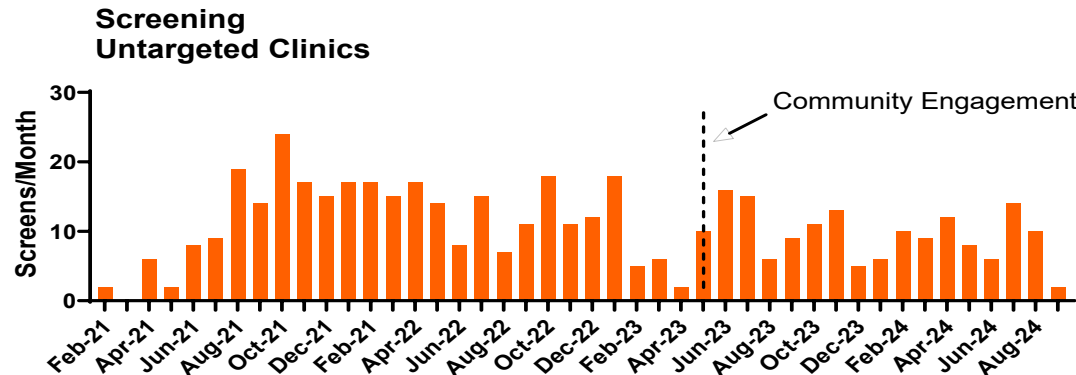
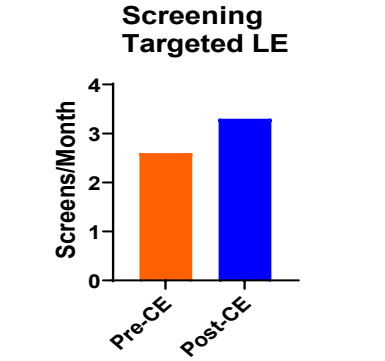
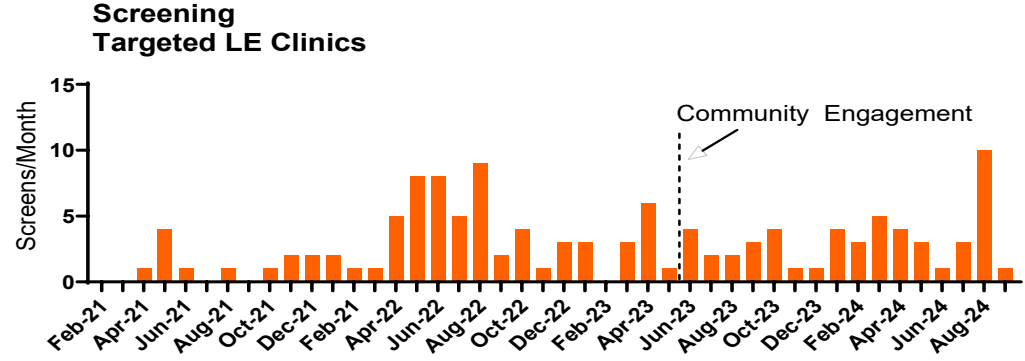
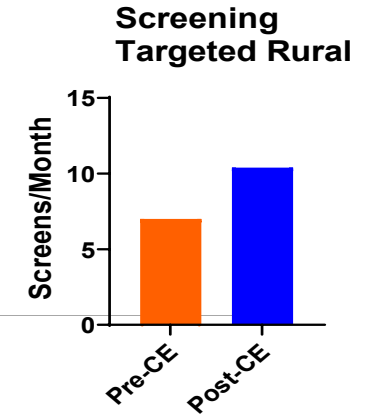
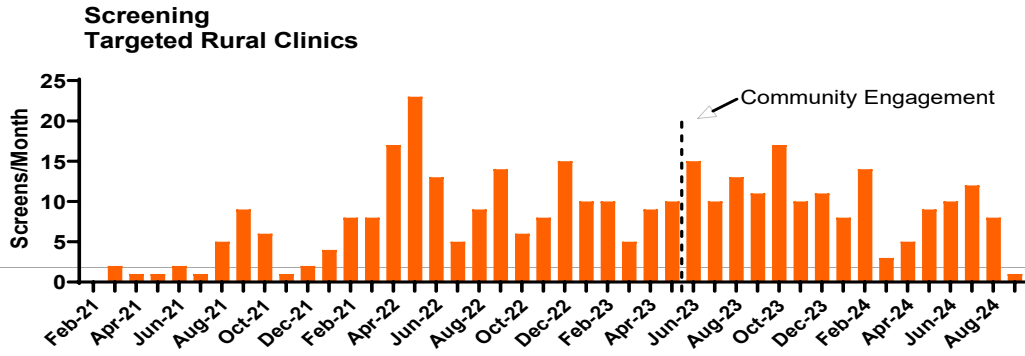


Clinics by Target

Pre and Post Community Engagement (CE)

Screening

- Rural
- Low Enrolling (LE)
- Untargeted



Key Points



- Community engagement makes a significant impact in a pragmatic trial
- Clinical research in community physical therapy clinics is not common
- Relationships with the clinic, clinicians and community are key components for the study team
- Community engagement process
 - Planning
 - Individual clinic plans through inquiry and feedback of clinicians and clinics
 - Implementation
 - Complete documentation and outcome measures
 - Assessment of activities
- Assessment of activities and plans lead to modifications, adaptations and changes

Questions?

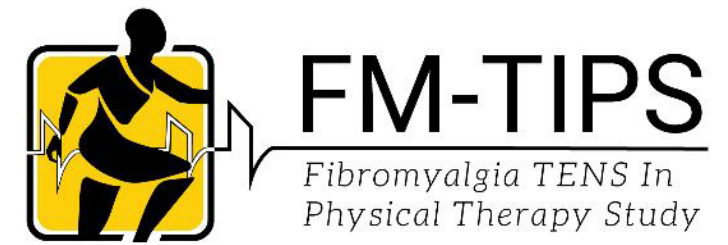


Contact information

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Study Website: www.fmtips.org

Thank You!



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FM-TIPS Team at University of Iowa and Vanderbilt University Medical Center

