



FM-TIPS

*Fibromyalgia TENS In
Physical Therapy Study*



VANDERBILT UNIVERSITY
MEDICAL CENTER

FM-TIPS Contact and Study Information



Email: FMTips-StudyTeam@uiowa.edu

Phone: 319-467-4203

iPad password: **932020**

Website: www.fmtips.org

Steps to log into clinician page on back of card

Clinician page password: ***fmtips@hcs2020***

FM-TIPS Study Team Representatives

APTSM:

Barb Van Gorp

barbara-vangorp@uiowa.edu

Genesis PT:

Dana Dailey

dana-dailey@uiowa.edu

Kepros PT:

Liz Johnson

elizabeth.m.johnson@vumc.org

RVPT:

Dana Dailey

dana-dailey@uiowa.edu

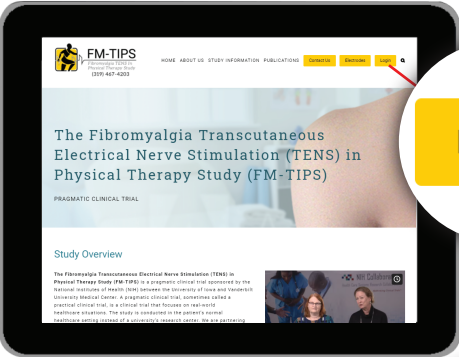
UIC PT:

Andrew Post

andrew-post@uiowa.edu

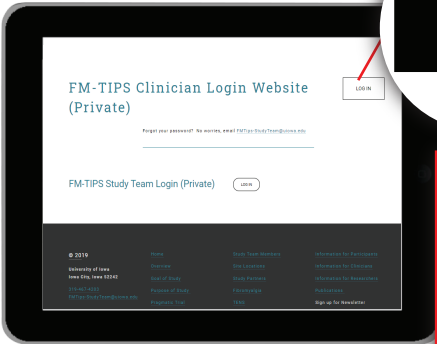
CLINICIAN LOGIN AND IMMEDIATE HELP CONTACTS

Our on-call study team is just a few clicks away



Login

Step 1. Log onto fmtips.org

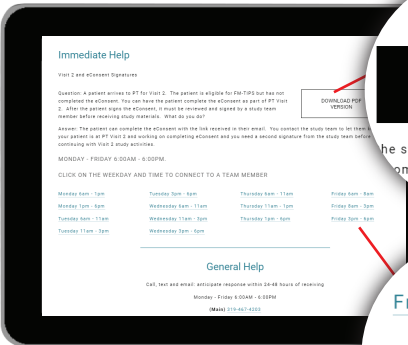


LOG IN

Step 2. Click on the "Log in" button

Step 3. Enter Password

[fmtips@hcs2020](#) →



DOWNLOAD PDF VERSION

Step 4. Download PDF

the study team to let them know
from the study team before

OR

[Friday 6am - 8am](#)
[Friday 8am - 3pm](#)
[Friday 3pm - 6pm](#)

If using a cell phone click on hyperlink with corresponding day/time for automatic call

Site Delegation Log

Study Title: Fibromyalgia TENS in Physical Therapy (FM-TIPS)

Name of the Study Site, City and State for This Log:

Instructions and Guidance for this form:

- The Principal Investigator (PI) for this site remains ultimately responsible for all aspects of the research study conducted at this site, regardless of whether study tasks are delegated to others or who serves as lead PI for the overall study.
- A copy of this log signed by this site's PI must be submitted to the research study team, who will submit it to the IRB of record with the new application or amendment, as appropriate.
- This log must be updated in a timely fashion as key personnel are added or removed. Updated logs must be submitted to the lead study team and submitted to the IRB of record for review.
- For the table below, select all Study Tasks* by number that apply:
 1. Participate in design of the study protocol,
 2. Identify potential subjects (e.g., chart review to identify potentially eligible subjects),
 3. Facilitate pre-enrollment screening,
 4. Perform study-related interventions and events,
 5. Dispense TENS units,
 6. Administer TENS as part of PT session,
 7. Other (Describe)

Name	Title	Study Tasks*	Start Date	End Date

PI Signature: _____ **Date:** _____

FOR LOCAL IRB POINT OF CONTACT (POC) USE ONLY

The personnel listed above

- Have adequate education, training, and qualifications to perform the research and safeguard the rights and welfare of research subjects;
AND (check one option below):
- ☐ No personnel have a potential financial conflict of interest associated with this study
- ☐ Some personnel have a potential financial conflict of interest associated with this study and are identified below.**

**Personnel with potential conflicts of interest

Name of person

IRB Point of Contact Signature: _____ **Date:** _____

IRB Point of Contact Printed Name: _____



FM-TIPS

*Fibromyalgia TENS In
Physical Therapy Study*

National Institutes of Health Funded Pragmatic Clinical Trial



No TENS

Clinician Manual

V2.0 11/22/21

University of Iowa
Vanderbilt University Medical Center



fmtips-studyteam@uiowa.edu

www.fmtips.org

Table of Contents

Welcome to the FM-TIPS Study!	3
Research Study Team.....	4
Contact the FM-TIPS Research Study Team	5
Clinician Feedback	5
Summary of the Study	6
Study Overview	6
Study Design	6
Study Participants – No TENS	7
PT Visit Research Events	8
PT Visit Overview	8
PT Visit 1 Pre-Enrollment Eligibility	8
PT Visit 2 eConsent and Enrollment Check.....	8
PT Visit 3 Research Homework Check	9
Participant Logging on to REDCap for Research Homework	9
Our data collection website it call REDCap.	9
PT Visits 1, 2, 3 Table	10
No TENS: Clinician Scripts for PT Visits	12
PT Visit 1: Study Events - No TENS	12
PT Visit 2: No TENS	14
PT Visit 2: Script Highlights - TENS.....	14
PT Visit 3: No TENS	15
PT Visits after day 60 if patient is in PT.....	16
Completion of the Study.....	17
Frequently Asked Questions (FAQ)	18
Appendix:.....	20
Outline of Study Initiation.....	21
PT Visits 1-3 Decision Tree.....	22
Patient Specific Functional Scale – PT Script	23
Sit and Stand Test	25
TENS Instructions	26
TENS Home Use Review	29
Quell Flex Quick Start Guide	31

Welcome to the FM-TIPS Study!

Thank you for being a part of the Fibromyalgia Transcutaneous Electrical Nerve Stimulation (TENS) in Physical Therapy Study (FM-TIPS). This is a pragmatic clinical trial sponsored by the National Institutes of Health (NIH) conducted by the University of Iowa and Vanderbilt University Medical Center. A pragmatic clinical trial, sometimes called a practical clinical trial, is a clinical trial that focuses on real-world healthcare situations. The study is conducted in the patient's normal healthcare setting instead of a university's research center.

The goal of the FM-TIPS study is to determine if the addition of TENS to physical therapy for patients with fibromyalgia helps to reduce pain, increase adherence to physical therapy, reach personal functional goals, and decrease medication use.

This manual contains what you will need to participate in this study:

- Summary of the research study
- How to contact the research study team
- Study Events for Clinicians
- TENS Instruction for your information
- Scripts for Study Events
- Frequently asked questions
- Completing the study

Thank you again for participating in the study. Please let us know if you have any questions.

Thank you,



Kathleen A. Sluka, PT, PhD
Co-Primary Investigator
University of Iowa
Center



Leslie J. Crofford, MD
Co-Primary Investigator
Vanderbilt University Medical

Research Study Team

Study Team Lead Investigators



Kathleen A. Sluka, PT, PhD, FAPTA

Professor

Department of Physical Therapy and Rehabilitation Science

University of Iowa

Iowa City, IA



Leslie, J. Crofford, MD

Professor and Chair

Division of Rheumatology & Immunology

Vanderbilt Medical Center

Nashville, TN

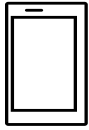
Study Team



Our team includes a group of investigators with diverse expertise including physical therapists, a rheumatologist, clinical trial specialists, and informational technologists.

Additional team members: Dana Dailey, Carol Vance, Dixie Ecklund, Carla Frank, Emine Bayman, Bridget Zimmerman, Michele Costigan, Maxine Koepp, Trevis Huff, George Nye, Rick Peters, Sandra Mostaert, Ruth Chimenti, Andrew Post, Maggie Spencer, Tina Neill-Hudson, Jon Yankey, Elizabeth Johnson, Barb Van Gorp, Adam Janowski, Zack Lemka, Kristin Archer

Contact the FM-TIPS Research Study Team



Quell Flex App: Search “Quell Flex” by NeuroMetrix



Email: fmtips-studyteam@uiowa.edu



Website: www.fmtips.org



Telephone: (319) 467- 4203



FM-TIPS Mailing Address:

Neurobiology of Pain Lab
Department of PTRS
University of Iowa
1-248 MEB, 500 Newton Rd
Iowa City, IA 52242

Clinician Feedback

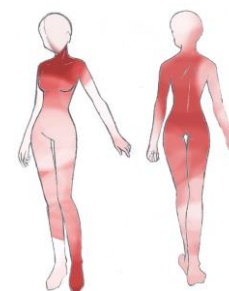
If there is a question or a problem, please get in touch with the research study team by calling (319) 467-4203 or sending an email to fmtips-studyteam@uiowa.edu.

Your honest concerns, questions and opinions are very much welcomed and also allow us to do anything we can to help. Make sure to give us a chance to address any issue you may have.

Summary of the Study

Study Overview

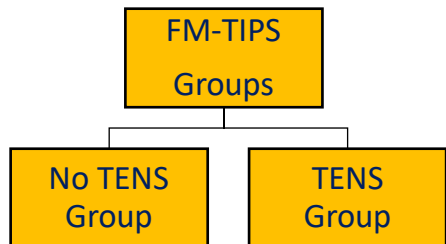
- Funded by the National Institutes of Health (NIH), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS); Pragmatic (real-world) clinical trial
- TENS is a safe and effective treatment for movement-evoked pain in FM patients
- Movement pain interferes with physical therapy exercises and activity participation
- TENS is underutilized by physical therapists and other health professionals
- Our recent NIH-funded randomized controlled clinical trial with participants with FM showed that active-TENS significantly reduced movement-evoked pain and fatigue after 1 month in-home use when compared to placebo-TENS and no-TENS (Dailey, et al. 2019; <https://onlinelibrary.wiley.com/doi/full/10.1002/art.41170>)
- The current NIH-funded pragmatic trial will test the following **goals**:
 1. Demonstrate the feasibility of adding TENS to usual physical therapy treatment of patients with FM in a real-world PT practice setting
 2. Determine if the addition of TENS to standard PT for FM reduces pain, increases adherence to PT and allows patients with FM to reach their specific functional goals with less drug use



Study Design

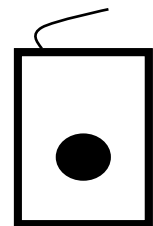
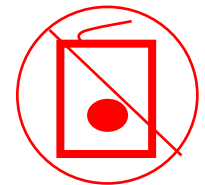
- More than 30 clinics in the Midwest .
- Each clinic will enroll 25 participants with FM (therapist will not confirm diagnosis) over the course of the 2-year study.
- Participants referred to physical therapy for fibromyalgia pain or for neck or back pain with FM as a secondary or co-morbid condition.
- Clinics will provide standard physical therapy care and clinics will be randomized to one of two groups:
 1. No TENS Group: Participants in this group will receive 2 TENS units after the first two months of the study to use at home for four months.
 2. TENS Group: Patients in this group will receive a TENS unit to use during their PT appointments and at home up to six months.
- Therapists will help with participant recruitment, Patient Specific Functional Scale, instruction of research activities, instruction of TENS use for the clinics participating in the TENS Group, and standard PT with or without the TENS unit.
- Research homework will be done at home at the start of the study and continue monthly for a total of 6 months.

Study Participants – No TENS



For FM-TIPS, we have 2 groups of participants, the No TENS group, and the TENS group. Both groups are very important to our study.

- Our goal is to have No TENS participants have standard PT treatment for the first 60 days of the study. After the first 60 days of the study, they will receive telehealth instructions with a research team member on how to use the TENS units at home for up to four months.
- Once they begin the TENS portion of the study after 60 days, our goal is to have the participants in the No TENS group wear the TENS units on their upper back and lower back for 2 hours per day, with a minimum of 30 minutes at a time. This means wearing the unit from 30 minutes for 2 hours and they may wear the TENS units for more than 2 hours a day.
- They should also wear the two TENS units during activity that occurs during their physical therapy visits if they are in therapy after the 60 days. They have flexibility in how they meet the 2 hours per day guideline. They can divide the time up or do it all at once.
- If they are unable to wear the TENS units for the full 2 hours or occasionally miss wearing the unit, we understand. Participants should open the Quell Flex App **at least once a week** to make sure both units are paired within the Quell Flex App to record their TENS use.

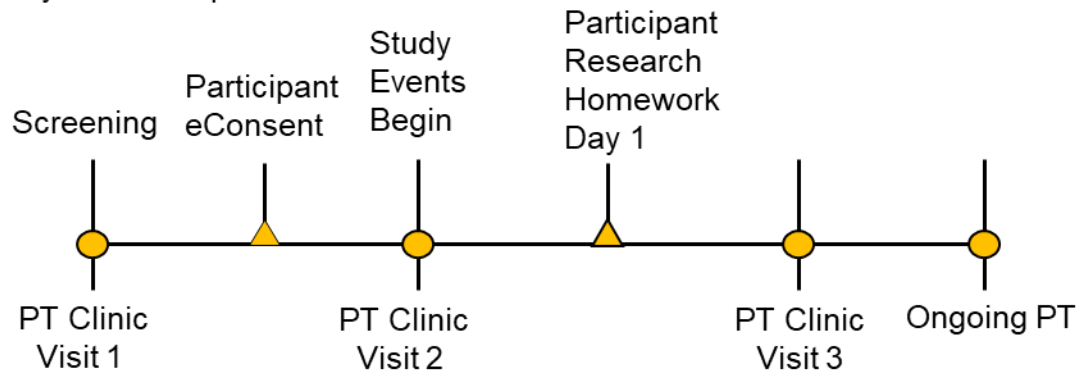


PT Visit Research Events

PT Visit Overview

The research study events for physical therapists include identifying possible participants on the initial PT Visit facilitating eligibility pre-screening on a tablet (Visit 1), confirming eConsent (PT Visit 2), and confirming completion of the participant research homework session (PT Visit 3).

Physical Therapist Events



Physical therapists will be responsible for initiating and monitoring research study events for PT Visits 1, 2 and 3. REDCap is an online data storage system that will collect information from all clinic sites in the study through a tablet or computer into a central database. Participants and clinicians will not have access to other participants' information. Data will be collected and accessed by the University of Iowa for analysis at the completion of the study.

PT Visit 1 Pre-Enrollment Eligibility



During the initial PT Visit (Visit 1), participants who are who are eligible to participate and are interested in being a part of the study, will complete an eligibility pre-screen in REDCap on a tablet in the clinic. Following the pre-screening, they receive an email letting them know if they are eligible or not eligible to be in the study.

PT Visit 2 eConsent and Enrollment Check



In REDCap, eligible participants will be given the opportunity to read and review the electronic Informed Consent (eConsent). They will also be advised to contact research study staff with questions or concerns within the document. After questions and concerns have been addressed, the participant will complete the eConsent form in REDCap.

Once the eConsent is completed by the patient, your site will receive an email confirmation that the eConsent has been completed. You will be expected to confirm that consent is completed prior to PT Clinic Visit 2. If you have any concerns that a participant has either not completed the eConsent or may not fully understand the study, please **DO NOT** perform any study procedures until you confirm the eConsent is appropriately completed with the study team at the University of Iowa.

After the participant completes the eConsent, you will receive a confirmation email so that you can perform study procedures as outlined in the protocol.

PT Visit 3 Research Homework Check



When participant returns on Visit #3, you will need to confirm that participant has completed their baseline research homework before proceeding. If they have not completed these assessments, they will be required to return the TENS units and be removed from the study.

Participant Logging on to REDCap for Research Homework



Our data collection website is called REDCap.

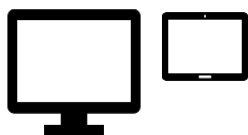


For the pre-enrollment eligibility checklist, your clinic will be given a tablet for your clinic that will have a link to the form the participants will complete for pre-enrollment screening.

This is just an example of a REDCap link and does not work

<https://redcap.icts.uiowa.edu/redcap/surveys/?s=XX32XXLMGHM>

Following eConsent, patients will be sent a link to complete each of the study research homework. Each time they click on the link, they will be able to complete research homework on REDCap – the data collection will go in this order:



- Rate pain and fatigue at rest
- Complete sit and stand test, rate pain and fatigue during the test
- Answer survey questions
- After 30 minutes, rate pain and fatigue
- Complete the sit and stand test and rate pain and fatigue during the test

PT Visits 1, 2, 3 Table

PT Visit	Physical Therapist Responsibility	Information to Know for this table (Words in blue are study continuation points) (Words in orange are study decision points) (Words in red are study stopping points)	Equipment or Materials Needed
PT Visit 1	Identify possible participant	Diagnoses: - Fibromyalgia - Neck pain and fibromyalgia - Back pain and fibromyalgia Inclusion Criteria • Age 18 or above • Clinician diagnosis of fibromyalgia (reported by patient) • Referred for land-based PT for treatment of FM or neck pain or back pain with FM as secondary diagnosis in past medical history • Able to provide informed consent • Fluent in reading English • Willing to use TENS Exclusion Criteria 1. Contraindications to TENS use (See Appendix 1 for Precautions and Contraindication references): a. Pacemaker, defibrillator, implanted neurostimulator or implanted device b. Epilepsy c. Currently pregnant or plan to become pregnant in the next 6 months d. Allergic reaction to patches with gel e. Current treatment for cancer 2. Currently enrolled in another pain control study 3. Use of TENS within the last 30 days 4. Clinically unstable medical or psychiatric issues	Recruitment Brochure
	PSFS	Patient Specific Functional Scale Measure completed during PT evaluation	Complete in electronic health record

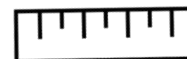
	Patient Interested or not	REDCap pre-screening on tablet in clinic If eligible, patient continues to eConsent. Patient must complete eConsent before visit 2 begins If not interested, declines.	Tablet
--	---------------------------	---	--------

PT Visit 2	Confirm eConsent completion	Check email to confirm eConsent completed If completed; continue If eConsent not complete: • Patient may complete eConsent on the tablet in the clinic prior to starting visit 2 • Patient may decline to participate	Email
	Study Procedures during Visit 2	Importance of Sit and Stand Test Study Supply	Study Supplies for No TENS Group Bag Participant Manual
PT Visit 3	Confirm Research Homework completion	Check email to confirm research homework completed • If research homework is incomplete, study ends • If research homework is completed, study continues Continue physical therapy per PT	Email
Ongoing PT	PSFS	PSFS completed if participant is in PT at day 30 and day 60	PSFS
If in PT after day 60	TENS	TENS during activity in PT clinic	TENS units and supplies (mailed to participant)

No TENS: Clinician Scripts for PT Visits

PT Visit 1: Study Events - No TENS

- Identify possible participant
 - Access to the internet
 - Able to provide informed eConsent
 - Able to read English well
 - Diagnosis of FM
- Patient Specific Functional Scale
 - See PSFS script and form in appendix
- Provide study information
- Patient to complete pre-enrollment screening on tablet



To Identify Possible Participant

- Screen all new patients with diagnosis of chronic neck or chronic back pain
 - The screen on the table takes less than 5 minutes
 - The screening on the tablet will ask about diagnosis of fibromyalgia by a clinician

PT Visit 1: Script Highlights – No TENS

Provide study information to participants

- We are conducting a study in partnership with the University of Iowa and Vanderbilt Medical Center to test a non-drug treatment for FM patients.
- We are testing the effect of combining TENS treatment with physical therapy for pain relief for individuals with fibromyalgia.
- The study team has done research showing that TENS helps to relieve fibromyalgia pain during activities like exercise or household chores.
- Now they want to see if using a TENS unit will make physical therapy easier and more productive.
- Compensation is included. And all the materials you will need are provided by the study team.
- Give patient flyer and point out contact information and other relevant points.
- Does this sound like something you're interested in?
 - If no: stop
 - If yes: continue

Pre-Enrollment Screening

- The next step is to have you answer screening questions on a tablet to determine if you meet the criteria to participate.
- Direct the patient to area where you want them to complete the tablet screening
- When you're done, return the tablet to the front desk staff.

eConsent

- If the patient is ready, patient can review the eConsent document and sign.
- If the eConsent is not signed at PT visit one the study team will contact the patient by email with materials to review and a document to sign. This will provide consent to participate in the research.
- Patient should contact the study team with questions and PT can answer questions at the next appointment.
- **Completion of eConsent as a requirement of being in the study**

PT Visit 2: No TENS

Study Activities

- Verify eligibility and eConsent - check email
- Sit and Stand Test Importance
- Continue with PT if time allows

PT Visit 2: Script Highlights - TENS

Eligibility and eConsent Verification

Eligibility

Visit 1- Fails screening

- Question: why don't I qualify?
- I am sorry you are not able to be in the study
- "The computer program scores the questions so I cannot really say. The study team sets criteria for participation.

eConsent

- If eConsent document has not been signed by the patient, the **patient MUST complete the eConsent** before continuing, electronically on tablet or participant's phone using link sent to patient by email.

Sit and Stand Test Importance

- I want to emphasize the importance of doing this "homework". It **must** be done before you come back for your next visit, (Give date if known) for you to continue in the study.
- There are several times when we ask you to rate your pain and fatigue on a 0-10 scale. These ratings are **very important** to our study team. You will do these ratings at rest and immediately after doing a test where you get up and down from a chair 5 times in a row.
- We are studying the effectiveness of TENS on rest and on movement pain, so these assessments are important now at the beginning, and all the way through the end of the study.

PT Visit 3: No TENS

Activities

- Verify Research Homework Completed
 - If participant does not complete Research Homework, discontinue participation
- Complete PT treatment
- Scenarios that may occur Visit 3
 - Change of heart about continuing in the study

Scenario	Therapist Script Ideas
No Research Homework Completed	I see that you did not complete the research homework for the TENS study. For participation in the study the surveys and testing done at home must be completed. I am sorry, but because we are missing that data point, we will have to end your participation. This means you will not receive the TENS units that come with being in the study. We will proceed with your physical therapy visits and if you're interested in TENS, I can include use of a different TENS unit as a part of the treatment.
Change of Heart	
I don't want to do this study	OK. Can you tell me a little detail about this decision? It is important for us to be able to make the study better. Possible reasons • <i>Money</i> • <i>Smart phone app too much for me</i> • <i>Time to put it all on</i> • <i>Anxiety with TENS</i> • <i>Did not help my pain</i> • <i>Itchiness with TENS</i> • <i>Hate the set up/can't get to my back</i> • <i>Nausea</i> • <i>No helper to get it set up</i> • <i>Skin irritation with TENS</i> • <i>Other</i>
The study is too much work	OK. The research homework can be a bit of work. You will receive the 2 TENS units and do the questionnaires and sit to stand test at home."
I have decided I do not want to participate (Final)	OK. Thank you for considering being part of the study and the time you spent on the study. Let's get started on your therapy."

PT Visits after day 60 if patient is in PT

After Day 60 of the study, participants will receive a telehealth instruction session on how to use the TENS units. If they are continuing in PT for the same encounter when they began the study, we ask that you use the TENS units during PT activity. Below are some scenarios that may occur:

Scenario	Therapist Script Ideas
TENS Units	
Participant forgot to bring TENS units and supplies or Participant brought TENS units and supplies but no charge	OK _____. For today I can use emergency backup TENS units and electrodes we have here in the clinic. Just a reminder this won't get captured on your TENS app for TENS use. <i>*** at the end of the session***</i> "Great work today. I am glad we were able to keep you in the study with our emergency backup equipment. For the rest of the visits, please remember to bring your supplies [TENS units, wires, electrodes] as this will help keep a more accurate record of your TENS usage. Make sure your units have a good charge before you arrive. Is there a good way you can think to help remind yourself to bring the study equipment [TENS units, wires, electrodes] /have the units charged each time?"
Participant suggests keeping TENS units and supplies in the car	That's not a great plan as you should be wearing the units during the day." "That's not a great plan because the units should not be kept in hot or cold temperatures" "What about this idea? Note on calendar, Phone reminder, post it note on frig? Note in the car

Change of Heart	
I don't want to do this TENS thing	OK. Can you tell me a little detail about this decision? It is important for us to be able to make the study better. Possible reasons • <i>Money</i> • <i>Time to put it all on</i> • <i>Did not help my pain</i> • <i>Hate the set up/can't get to my back</i> • <i>No helper to get it set up</i> • <i>Smart phone app too much for me</i> • <i>Anxiety with TENS</i> • <i>Itchiness with TENS</i> • <i>Nausea</i> • <i>Skin irritation with TENS</i> • <i>Other</i>
The study is too much work	OK. The research homework can be a bit of work, but from here on out will just be using TENS at clinic visit and at home. You will do the questionnaires and sit to stand test every 30 days.
I do not like the TENS units at all.	It is always your decision to participate in the study. Before you decide for sure, can you tell me more about why you did not like TENS?" Are you willing to have me set it up today and make sure everything is set correctly?"
I brought my equipment and supplies to PT Clinic and I do not want to continue	Ok. You may keep the bag if you would like. I will take your study equipment and process it for return. Thank you for your feedback." Let's get started with your therapy"
I have decided I do not want to participate (Final)	OK. Bring it to your next visit or drop it by to the front desk. After we account for the equipment [Two TENS, two wires, electrodes, case, and pouch] we will process your payment for the time you spent on the study. Let's get started on your therapy."

Completion of the Study

The study activities for participants will be completed after 6 months of participation. They will be able to keep the TENS units when the study is complete. They may contact the manufacturer, Quell, for more electrodes to purchase.

Frequently Asked Questions (FAQ)

1. Are participants paid for participating in the study?

Yes, each will be paid a total of \$200 if they complete all study visits. They will also receive 2 free TENS units and electrodes for 4 months. If they do not complete all study visits, they will be paid for the visits they complete on a pro-rated basis.

2. Can a study participant end participation in the study at any time?

Yes, they can contact the research study team by phone or email to end their participation.

3. Will there be any additional cost to study participants for participating in the study?

No, there will be no extra cost to the study participant.

4. What happens if a study participant becomes sick or injured during participation in the study?

The study participant should contact Dr. Dana Dailey or Dr. Kathleen Sluka as soon as possible to determine if it is safe for them to continue in the study.

Dr. Dana Dailey or Dr. Kathleen Sluka 319-467-4203.

5. What happens if a study participant becomes pregnant during participation in the study?

They should stop using the TENS unit immediately and contact Dr. Dana Dailey or Dr. Kathleen Sluka as soon as possible.

Dr. Dana Dailey or Dr. Kathleen Sluka 319-467-4203.

6. Can a study participant take all of their normal medications while using a TENS unit?

Yes, they should continue with medications as usual.

7. Can a study participant continue other treatments while using a TENS unit, i.e. acupuncture?

Yes, and if you have questions, please contact the research study team.

8. Will a study participant's individual information from the study be shared?

No, results from the study will only be shared as aggregate results or as de-identified data if any individual results are shared.

9. What are the risks associated with TENS treatment?

Study participants may experience local skin irritation (caused by the adhesive in the TENS electrode pad), mild redness at the site of the TENS stimulation and a burning or pricking sensation, discomfort or aggravation of pain from TENS.

10. Will using a TENS unit restrict activities?

The only activities limited while using a TENS unit are those associated with water, i.e. bathing, showering, swimming, etc.

11. What are the alternative options if a patient chooses not to do this study?

They could receive standard physical therapy without TENS, or you could discuss the use of an alternate TENS unit with them and the therapy could be performed without participation in the study.

12. Will the clinic be paid as part of being in the study?

Yes, for each participant enrolled, your clinic will receive \$200 to cover the cost of participating as a clinician in the study.

13. What if a participant does not want to continue in the study?

The participant can stop enrollment at any time and will need to contact the study team. Also, they can continue with their usual physical therapy care.

14. When should a patient return their TENS unit?

If a participant has not completed their research homework prior to Visit 3, then the TENS unit should be re-collected by the PT.

15. What do I do with any TENS unit that is returned/re-collected from a participant?

If a TENS unit is returned or re-collected, the unit will be returned to the study team

Appendix:

The appendix has forms that we will laminate for you to use in the study along with the scripts from Visit 1, 2 and 3.

- Outline of Study Initiation
- V1, V2, V3 Decision Tree
- PSFS Script and Scale
- Sit and stand test

The final section of the appendix has the TENS instruction section from the TENS portion that will occur after 60 days. This is for your information and includes:

- TENS Instructions
- TENS Home Use Review
- Quell Flex Application (App)

Outline of Study Initiation

PT Visit 1: Eligibility and study introduction

Complete Patient Specific Functional Scale during evaluation
Identify possible participants for the study
Give brochure to interested patients
If interested, have patient complete screening on tablet
Patient will need to complete eConsent on REDCap prior to Visit 2

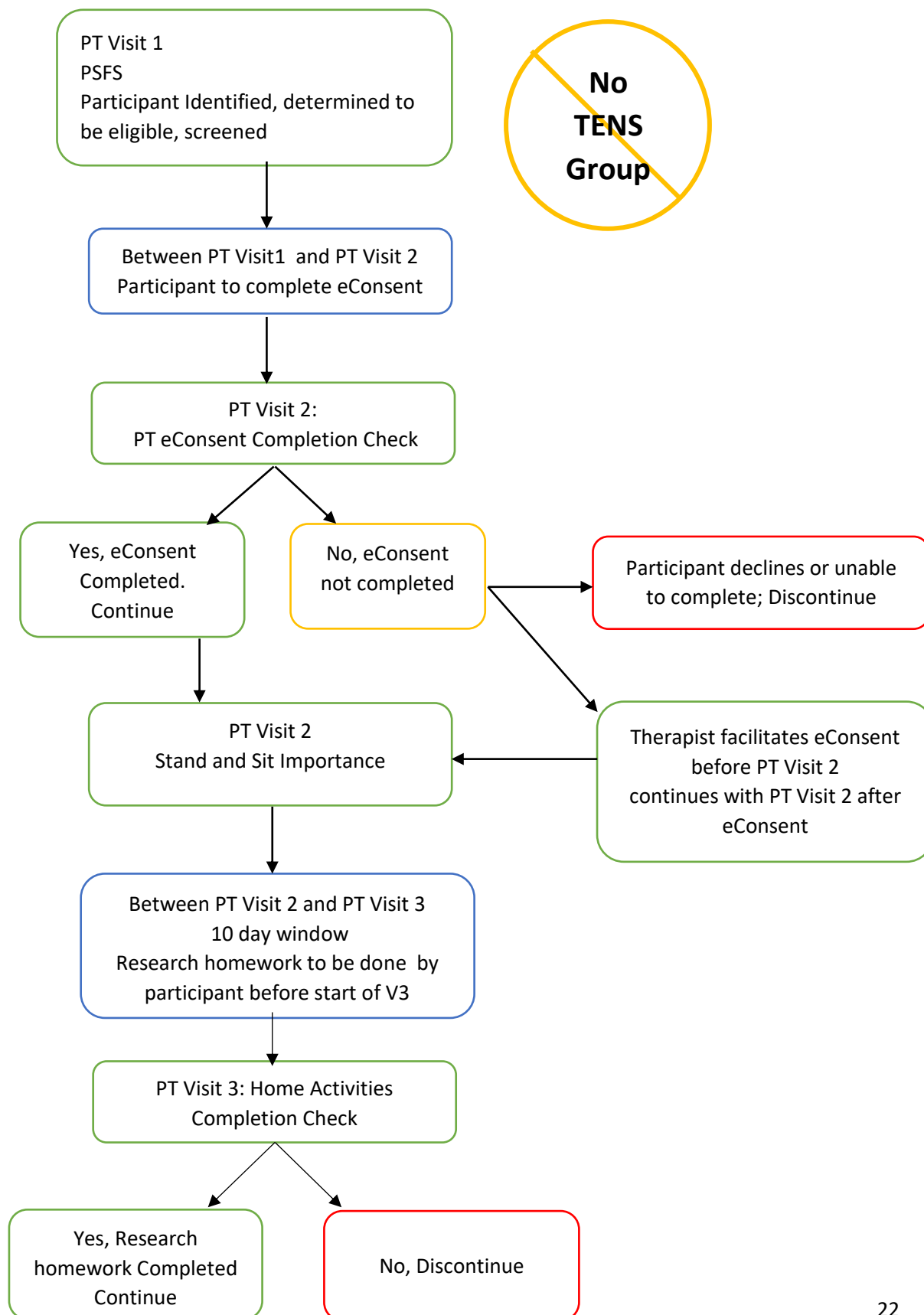
PT Visit 2: eConsent and Instruction

Check on eConsent completion, if not completed offer tablet or patient declines
If eConsent completed, begin study activities
Sit and Stand Importance
Study Supplies given to patient

PT Visit 3: Research Homework Check

Check on completion of research homework
Complete PT treatment
If participant does not complete Research homework, study ends

PT Visits 1-3 Decision Tree



Patient Specific Functional Scale – PT Script

PT to complete PSFS at Initial Evaluation and every 30 days while in PT

Clinician:

- We are going to complete an outcome measure called the Patient-Specific Functional Scale
- For this measure, I will need you to select 2 activities that are you are having difficulty doing because of the pain or symptoms you are experiencing.
- The selected activities can be any task you complete during a typical day that you notice are impacted by your pain or symptoms.
- *If patient has difficulty reporting specific activities, the clinician can provide examples of activities with patient based on subjective examination and reported functional limitations*

Patient:

Patient selects at least 2 activities (can select up to 5)

Clinician:

- That is a great set of activities that you selected
- Next, I am going to have you rate how much difficulty you are having completing each specific activity on a scale of 0 to 10. Please note, this scale is an activity scale, and it is opposite of the pain scale
- “0” means that you are unable to complete the activity and “10” means you are having no difficulty performing the activity or at a level prior to your condition.
- *Clinician establishes that the patient understands the scale as this is a reverse scale outcome measure.*

Patient:

- Patient provides rating on 0-10 scale for at least 2 separate activities.
- *Patient reported value is then recorded by PT for each activity*

PSFS Scoring

- Total Score = sum of the activity scores/number of activities
- Minimum detectable change (90%CI) for average score = 2 points
- Minimum detectable change (90%CI) for a single activity score = 3 points

Patient Specific Functional Scale FM TIPS

0
Unable to
perform activity

10
Able to perform
activity at the same
level as before
injury or problem

0 1 2 3 4 5 6 7 8 9 10

Sit and Stand Test

The purpose of this test is to examine your pain during an activity.

Your goal is to rate your pain and fatigue **BEFORE** you do your activity and then **DURING** the activity.

Activity: Standing up and sitting down from a chair 5 times

What you need to do the test:

- Standard hard-back kitchen chair without wheels
- [with arms if possible]
- Comfortable walking shoes
- Computer/tablet



How to do the sit and stand test:

1. Wear comfortable shoes (No sandals/slippers/bare feet).
2. Find a place to put your chair so it won't move [against the wall or against a stable object such as a table].
3. The chair should be in a location in your home where your computer/tablet/smartphone is close so you can enter pain and fatigue ratings.
4. Rate your pain and fatigue **BEFORE** you do the activity and record in REDCap.
5. Stand up and sit down from the chair 5 times.
6. Rate your pain and fatigue after you do the activity. You should rate your pain and fatigue at the highest rating that occurred **DURING** the activity and record it in REDCap.
7. Now you are ready to begin the test!



Step 1: Rate your pain and fatigue and record it in REDCap on your computer or tablet

Step 2: Perform the Activity

1. Sit on the chair. Place your feet shoulder width apart.
2. Rise up to a full standing position and then sit back down just so that your bottom and the back of your thighs make full contact with the chair [no need to have back touch the backrest]. If your chair has arm rests, don't use them unless you need them.
3. Stand up and sit down four more times as quickly and safely as possible (total of 5 times standing and sitting).



Step 3: Rate pain and fatigue and record it in REDCap on the computer or tablet at the highest rating the occurred during the activity.

TENS Instructions

This section is included for your information as a physical therapist and if you need some help if your patient has the TENS units on after the 60 day mark. They will receive a telehealth instruction visit for instruction in the use of TENS.

See TENS Manual for more detailed instructions, Contraindications and Precautions

Quell Flex Smartphone Application – Download and Pairing

Download the Quell Flex App on patients smartphone



Serial number entered by patient into app

- Help patient **pair** the TENS units
- Instruct the patient to open the app **once per week** so the usage data can be downloaded to the study personnel.

While app is downloading: let's look at all your study materials

Manuals and Guide

- | | |
|--------------------------|--------------------------------|
| • TENS Group Participant | • Quell Flex App Manual |
| • Quell Flex TENS Manual | • Quell Flex Quick Start Guide |

TENS Equipment

- | | |
|---------------------------------|--------------------|
| • 2 TENS units | • 1 carrying pouch |
| • 2 color coded wires | • 1 case |
| • 2 chargers and 2 charge cords | • 10 electrodes |

Quell Flex TENS Units

- If needed, review description of TENS for patient, see appendix for example
- 2 TENS units: **Upper back – purple** and **Lower back – orange** connect wires to units
- Therapist uses one TENS unit and patient uses the second TENS unit
 - (Patient mirrors therapists demonstration)
- Connect color coded wires to colored units
- Connect wires to electrodes
- Clean skin, apply electrodes to upper and lower back
- Begin TENS treatment and pair both TENS units to the Quell App



- Review TENS intensity increase and decrease with the blue button and Quell Flex App
 - Gradually increase the intensity until the patient feels a strong, comfortable, non-painful sensation.
 - As users get used to the sensation, they are often able to turn the unit up further after a few minutes of wear. It is important to keep this in mind as the patient wears it at home.
 - The unit will max out at an intensity of 100 mA.
- Electrode placement, use and care
- Review stopping a treatment with the blue button and the Quell Flex App
- Review TENS units charging – charging port, time to recharge and charger itself
- Explain lights on the TENS units
 -  ○ Single white flashing light – unit is charged and ready for treatment
 -  ○ Double white flashing light – TENS treatment is active
 -  ○ Blue light – poor connectivity (electrode, wire out of unit, wire out of electrode)
 -  ○ No light when the start button is pressed – time to charge the unit
- Resetting the TENS Unit
 - The Quell Flex TENS units automatically ramp up to the last intensity used. Clinics and participants may want to reset the units to the default of 5mA, the lowest setting.
 - While the TENS unit is off, press and hold the button for 2s (until rapid blinking of the white light is shown).
 - The unit then ramps up to 5mA [over 2 minutes] the first time you run a treatment.
 - Patients are then to increase to “strong but comfortable” for the session.
 - The next time they start a session, the unit ramps up to the last mA they utilized. They should further increase/decrease intensity to “strong but comfortable” for every session.
 - Remember, the number does not matter, the sensation of “as strong as possible while still being comfortable” is important. Intensity is linked to effectiveness!

TENS use at home



Participants are asked to use the two TENS units to the upper back and lower back for 2 hours a day. We ask that they use during activities in the clinic and for a minimum of 30 minutes per session. They are welcome to break up the sessions through the day or do them all at once. Please assist the participant to find what works best for them. They may use the TENS units for more than 2 hours. They should try to wear them when active. "Do what works for you."

TENS Use during PT sessions



Participants are asked to bring their TENS units to each physical therapy session. They should use them during activities in the clinic and for a minimum of 30 minutes. This means that they may need to finish the TENS session after the PT session has ended. \

Operating the TENS unit



You will be given a separate booklet with instructions for operating the TENS units. If you have a question or a concern, please call or email the research study team.

Quell Flex TENS Application, (App)



You will be given a separate booklet for the Quell Flex App. Please remind the participant to log into the application **at least once a week** so that their TENS wearing time is recorded.

Quell Flex Quick Start Guide



The Quell Flex App Quick Start guide is meant to be used in conjunction with the TENS Manual. It is an outline of the manual for a quick reference for starting and ending a treatment and pairing the TENS units on the smartphone application.

TENS Home Use Review

See TENS Manual for more details

Research has shown that a minimum of 30 min TENS application is required to receive benefits, so once you turn on the TENS units, please wear it for a minimum of 30 minutes.

For this study we are asking that you wear the TENS for 120 minutes each day during activity. This can be as one continuous session or multiple 30 minute sessions.

You may use the TENS as often as you would like, including exceeding the 120 minutes per day.

Research has also shown that TENS works best for pain during activities but not when sitting still or laying down.

For this study you are asked to wear the TENS units **when moving around**. Examples include exercise, walking, household chores or working.

- For the purpose of this study we ask that you **wear the electrodes on your upper back and your lower back**.
- For this study we ask that you wear them in the designated spots so that we collect good data.
- Also, we ask that you **wear both units** at the same time. Refrain from only turning on one unit. If you have a reason preventing you for using it at both locations, please contact the study team.
- The units record information for the study, such as number of sessions, average intensities, total wear time etc. so make sure **you are the only person wearing** them.
- After this study is over, you will keep your units and can use them for other areas of pain. The Quell support team will be able to assist you with the TENS units after the study is over.
- **Electrodes are designed to last 10-14 days**. We ask that you get as many wears out of one electrode as long as it remains sticky and in good condition. It is important to keep the electrodes on the plastic insert, inside of the zipped package when you are not wearing them. This will keep them sticky for a longer period of time.
- If you **notice the corners start becoming un-sticky** you can wet your fingertip, run it over the electrode to get it damp/ slightly wet and let it air dry for 30 seconds. This will allow the electrode to become tacky.

- For a good TENS treatment it's important for you to **keep your skin clean** (even if it's with a wet washcloth before applying the electrodes) and the electrodes sticky for better electrical conduction.
- It can be beneficial to warm up the electrodes by holding them in your hands for a few minutes prior to putting them on.

If you wear the unit for 30 minutes and you want to take a break, you can always shut off the unit but leave the electrodes on and you can roll up the wires and put them in a pocket. This will save you a step or two when hooking up the unit for the next session.

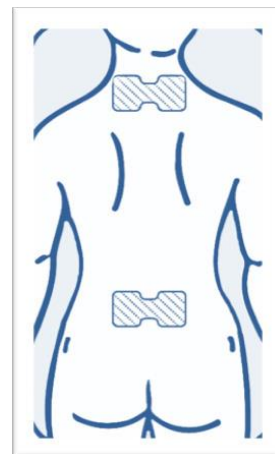
- This will also keep the electrodes sticky for a longer period of time by decreasing the number of times you put them on and take them off.
- **The supply of electrodes is intended to last 2 months.** Cleaning your skin and keeping the electrodes on the plastic and in the bag when not in use is important to keep them in good shape for as long as possible.
- The study team will send you more electrodes after the 60-day (2 month) check-in. If you need some sooner, you can contact the study team for more.
- Help patient to think about their daily routine and **identify times** when she can/should wear her TENS unit.
 - While doing housework
 - While getting ready in the morning (not in the shower or bath)
 - While taking an evening walk
 - While shopping or running errands
 - While doing PT exercises at home
 - While at work

Remind patient of contact information for the study team and Quell that is found in the TENS unit materials. The patient is encouraged to reach out for help and questions as needed.

Quell Flex Quick Start Guide

To begin a treatment:

1. Make sure the TENS units are OFF and fully charged.
2. The charger port is on the side of the unit. A full charge will take 1.5-2 hours.
3. Remove the unit from the wall charger.
4. Attach the lead wires to the electrodes.
5. Apply electrodes to clean dry skin.
6. Attach the color-coded lead wires to the TENS unit.
7. Turn the unit ON by pressing the blue button on the front.
8. The white light on the top of the unit will flash. (two quick flashes)
9. The stimulation will increase to a set level over two minutes.
10. Increase the intensity to be strong but comfortable by holding down the blue button.
11. After a few minutes, it may seem the stimulation has gone down. This is normal as your body gets used to the TENS.
12. You should turn up the intensity to keep it feeling strong, but comfortable.
13. Decrease the intensity by pressing and releasing the button.
14. The timer automatically sets for 60 minutes.
15. You may use the unit as much as desired.
16. For the study, we are asking you to wear TENS for 2 hours each day.
17. Wear the unit for a minimum of 30 minutes each session.
18. Try to wear your TENS when active.

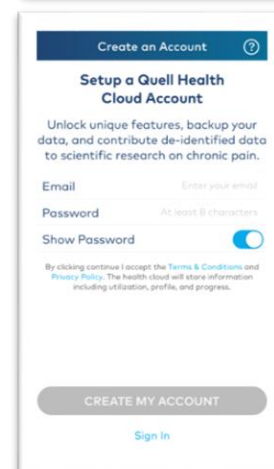
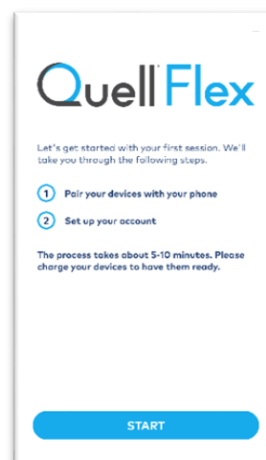


To end a treatment:

1. Press and release the blue button 4 times in a row.
2. You may keep the electrodes in place for your next treatment.
3. Secure the units and wires in the pouch or a pocket.
4. If you see a flashing yellow light, it means there is a problem with connectivity. Turn the unit OFF. Check to make sure the wires are inserted into the unit as well as into the electrodes. Also, check to make sure your electrodes have good contact with your skin.
5. When you are finished with treatments for the day, remove your electrodes.
6. Find the white non-sticky section in the middle.
7. Gently pull to release the electrode. Hold your skin down next to the electrode as it releases.
8. Return the electrode to the plastic sheet and place in the zip lock bag.

Using the Quell Flex Application (App):

1. Using your mobile device or tablet, open the App Store or Google Play
2. Search “Quell Flex” by NeuroMetrix and download the app to your device.
3. Make sure Bluetooth is turned on and that your device is running iOS 10 or later, or Android 6 or later.
4. Launch the Quell Flex App and follow the step-by-step instruction within the app to pair both Quell TENS units.
5. Instructions within the app will guide you through two steps:
 - Set up your Health Cloud Account
 - Pair your devices with the phone
6. Creating a Health Cloud Account
 - For the email address, enter your unique study ID that you will receive from the research study team (for example XXXX from site YY) to TIPSYYXXXX@quellrelief.com
 - Password: **dailytens**
7. You will pair both the “Upper” and “Lower” Quell TENS units. Once you enter the last two digits, the device will recognize your Quell Unit as either “Upper” or “Lower.”
8. **In order to capture your TENS use, we need you to open the app and make sure both units are paired within the Quell Flex App at least once a week.**



For complete FM-TIPS Quell Flex instructions please refer to your Quell Flex TENS Manual and Quell Flex App Manual!



FM-TIPS

*Fibromyalgia TENS In
Physical Therapy Study*

Onsite Clinician Training



No TENS Clinic

University of Iowa

Vanderbilt University Medical Center



Introductions and Importance of FM-TIPS

Introductions



- What is a pragmatic trial?
 - Real world setting: OP PT Clinics
- This is an important trial – robust trial of nonpharmacological treatment for pain
- Integrated team of clinicians and scientists
- High impact for PT knowledge base and foundation for future PT clinical research
- Pragmatic trials are the future



Plan for Today



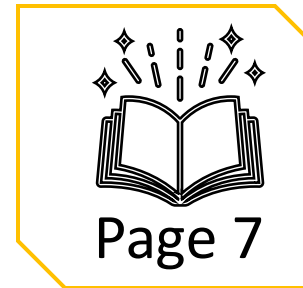
- Introduction
- Importance of FM-TIPS
- Goals for FM-TIPS
- TENS Evidence
- Materials
- Highlight Participant Activities and PT critical decisions
- Quell Flex TENS Introduction
- Return Demonstration
- Role Play with Scripts
- Clinic Planning for Study Activities
- What Not to Do
- Questions and discussion
- Next Steps

FM-TIPS Goals

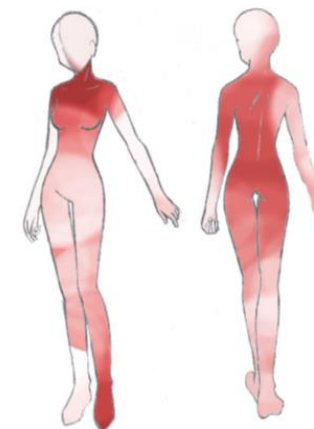
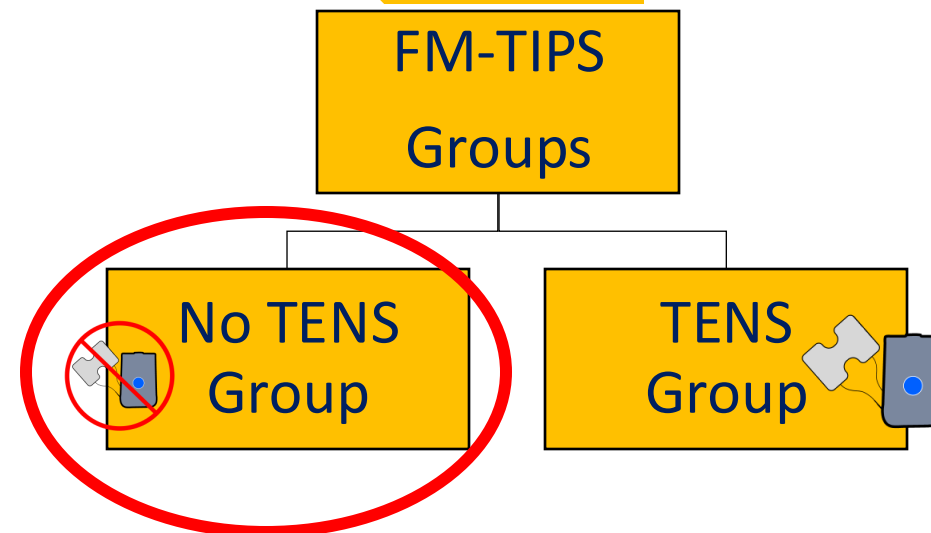
1. Demonstrate the feasibility of adding TENS to usual physical therapy treatment of patients with FM in a real-world PT practice setting
2. Determine if the addition of TENS to standard PT for FM reduces pain, increases adherence to PT and allows patients with FM to reach their specific functional goals with less drug use

Last Enrollment:
December 2023

December 2023						
Su	M	T	W	Th	F	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						



Page 7



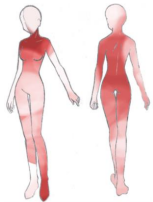
1/month



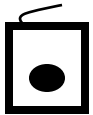
Why TENS?



- Exercise is a recommended intervention for patients with fibromyalgia



- Fibromyalgia patients have increased pain with exercise



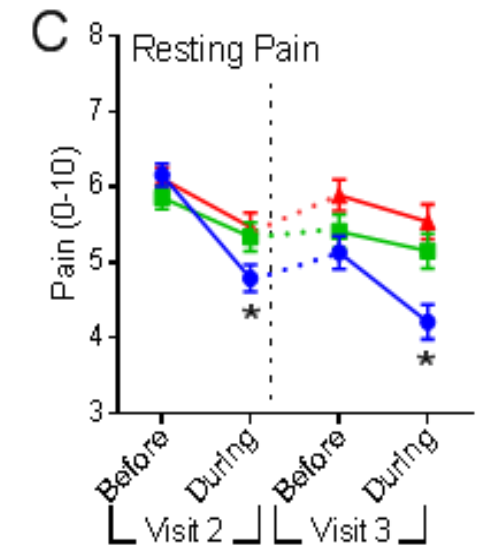
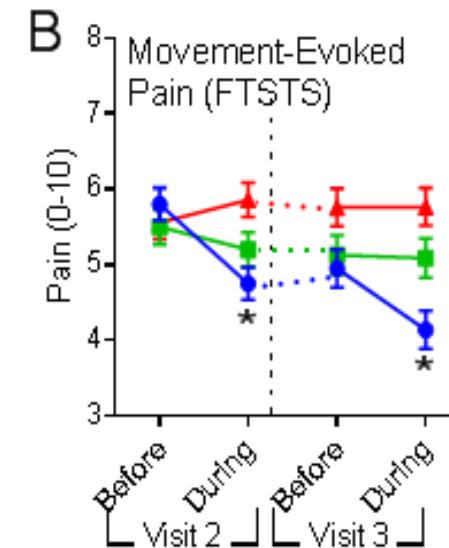
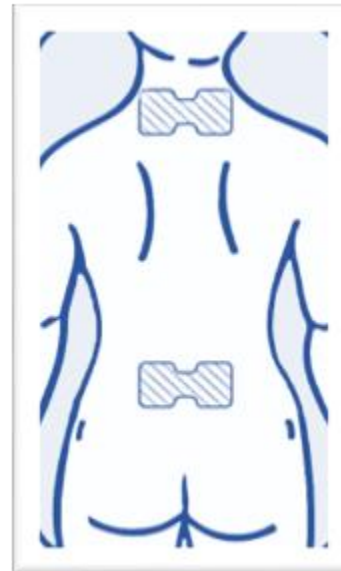
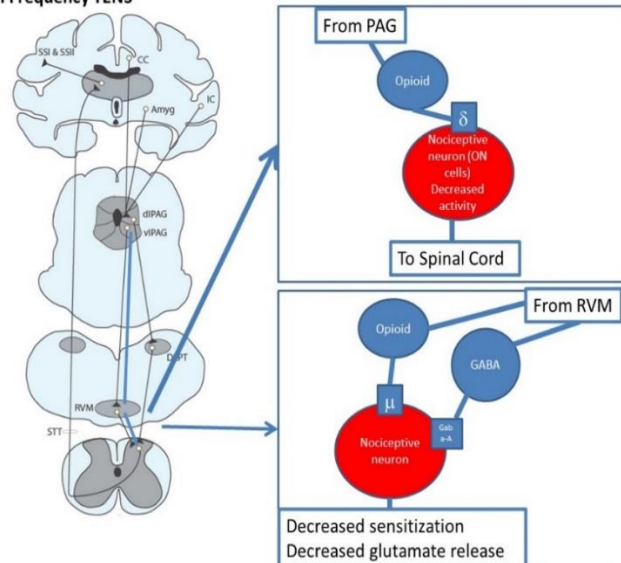
- TENS reduces pain and fatigue with movement!



Review of TENS Evidence

- Parameters are important for success – intensity, frequency, duration, and activity
- Discussion about TENS evidence
- Reference List (last slide) If you would like a copy of a paper, please us know.

High Frequency TENS





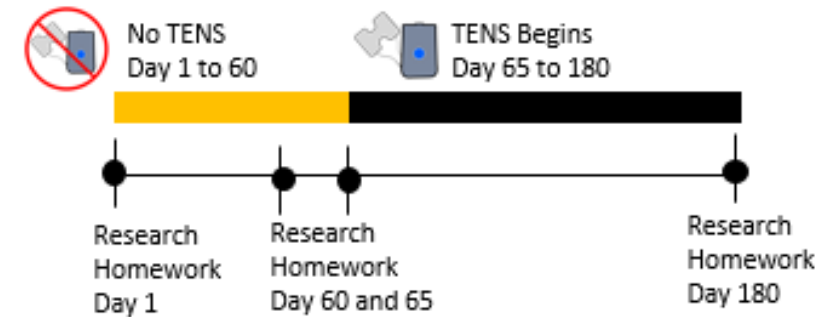
Study Materials: No TENS Group

Clinician Materials

- No TENS Clinician Manual
- No TENS Electrodes for practicing
- FM-TIPS Pen
- Contact Card

Participant Materials in the Bag

- No TENS Participant Manual
- Study Bag, Pen





Study Materials: No TENS Group



Clinic Materials

- Flyers, Brochures, Pens
- No TENS Clinician and Participant Manual
- Clinic Quell Flex TENS Units (2) and QuickStart Guide
- Quell Flex TENS and App Booklets
- Laminated Forms (2 sets)
- iPad
- Report Folder
 - Report Cover with clinic number
 - iPad Cheat Sheet
 - Best Practices
 - TENS Receipt Form
 - TENS Accountability Log

Clinic Plans for Success!!!

- Post Flyers in your clinic
- Place brochures where you can access them easily
- Plan to identify possible participants on schedule or folder – weekly is best
- Screening plan for all new patients with neck and back pain (best practices)
- iPad charging
- TENS unit charging (charge lasts 2 weeks)
- Storage plan for participant bags

Identify Possible Participants



Therapist Identifies:

- Neck pain and fibromyalgia
- Back pain and fibromyalgia
- Fibromyalgia
- Stable medically or psychologically

Criteria covered in the iPad Screen

Inclusion Criteria

- Age 18 or above
- Clinician diagnosis of fibromyalgia (patient reported)
- Able to provide informed consent
- Fluent in reading English
- Willing to use TENS

Exclusion Criteria

- *Clinically unstable medical or psychiatric issues*
- Currently enrolled in another pain control study
- Use of TENS within the last 30 days
- Contraindications to TENS:
 - Pacemaker, defibrillator, implanted neurostimulator or implanted device, Epilepsy, Currently pregnant or plan to become pregnant in the next 6 months
- Allergic reaction to patches with gel

iPad Screening p.1



REDCap

Click on the
REDCap Icon on
the iPad when
you are ready
to have your
patient screen.

Please feel free to ask questions at any time by contacting our team. Here are a few ways to contact us:

- Telephone: 319-467-4203
- Email: fmtips-icf@uiowa.edu
- Website: fmtips.org

If you are interested in participating in the FM-TIPS study, the next step is to answer a few screening questions to see if you qualify for FM-TIPS.

I have read the above information and would like to complete the screening questions.

* must provide value

☐ No ☐ Yes

First name:

* must provide value



Last name:

* must provide value



Phone Number:



Study notifications and communication are through email,
phone and text messages. If you would like to
opt out of the text messaging please check the box to the right.



☐ Click here to opt out

iPad Screening p.2

Site: * must provide value	(H)	
Email address (Used for study access and communication) * must provide value	(H)	
	No	Yes
Are you 18 years of age or older? * must provide value	(H) ☐	☐
Have you been told you have fibromyalgia by a physician or other clinician? * must provide value	(H) ☐	☐
Are you currently starting physical therapy for neck pain or back pain or fibromyalgia? * must provide value	(H) ☐	☐
Are you able to read English well? * must provide value	(H) ☐	☐
Are you willing to wear a TENS unit and electrodes for your neck and back? * must provide value	(H) ☐	☐

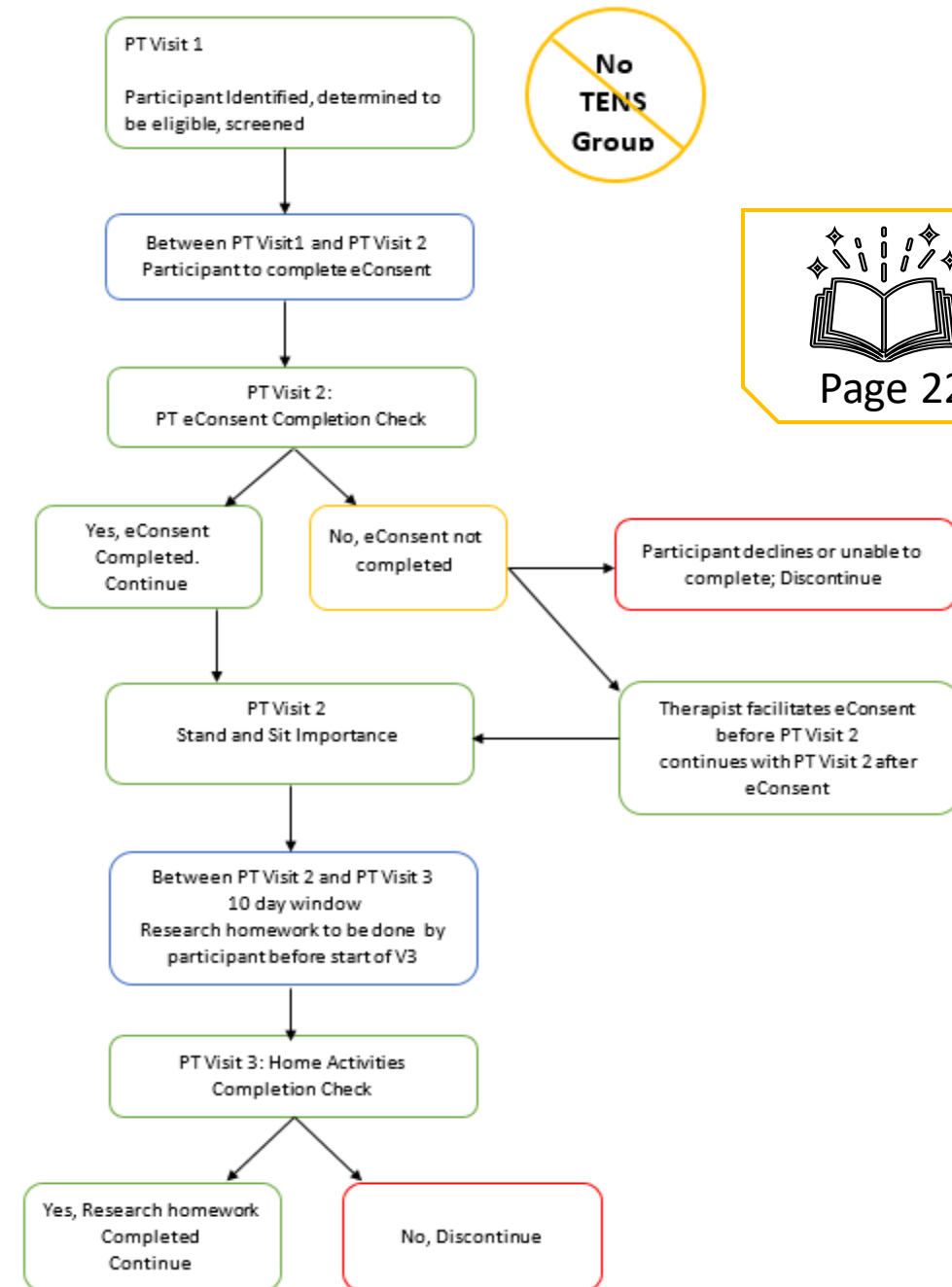
iPad Screening p.3

	No	Yes
Do you have an implanted device that is controlled electronically such as a pacemaker, defibrillator, or neurostimulator? * must provide value	☐	☐
Are you currently enrolled in another research study for pain control? * must provide value	☐	☐
Have you used TENS in the last 30 days? * must provide value	☐	☐
Do you have epilepsy? * must provide value	☐	☐
Are you being treated for active cancer? * must provide value	☐	☐
Are you currently pregnant or planning to become pregnant in the next 6 months? * must provide value	☐	☐
Do you have an allergic reaction to gel pads on your skin - similar to the gel on an EKG patch? * must provide value	☐	☐
Thank you for taking the time to answer the FM-TIPS screening questions. Based on your answers, we are sorry, but you do not qualify to participate in the study. Please feel free to ask questions by contacting our research study team. Here are a few ways to contact us: • Telephone: 319.382.0834 • Email: fmtipsstudyteam@gmail.com • Website: fmtips.org You will also receive an email with this information		
Id field		View equation
Form Status		
Complete?	Incomplete	

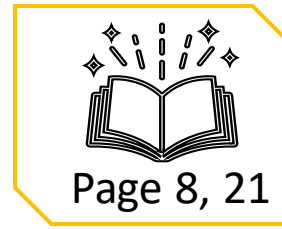


PT Decision Points

- **PT Visit 1:**
 - Identify possible participant
 - Pre-enrollment screen on tablet
- **PT Visit 2:**
 - eConsent Check
 - Importance of Sit and Stand Test and Homework Importance
- **PT Visit 3:**
 - Research Homework Day 1 Check



Events in PT Visits 1 to PT Visit 3



PT Visit 1: Eligibility and study introduction

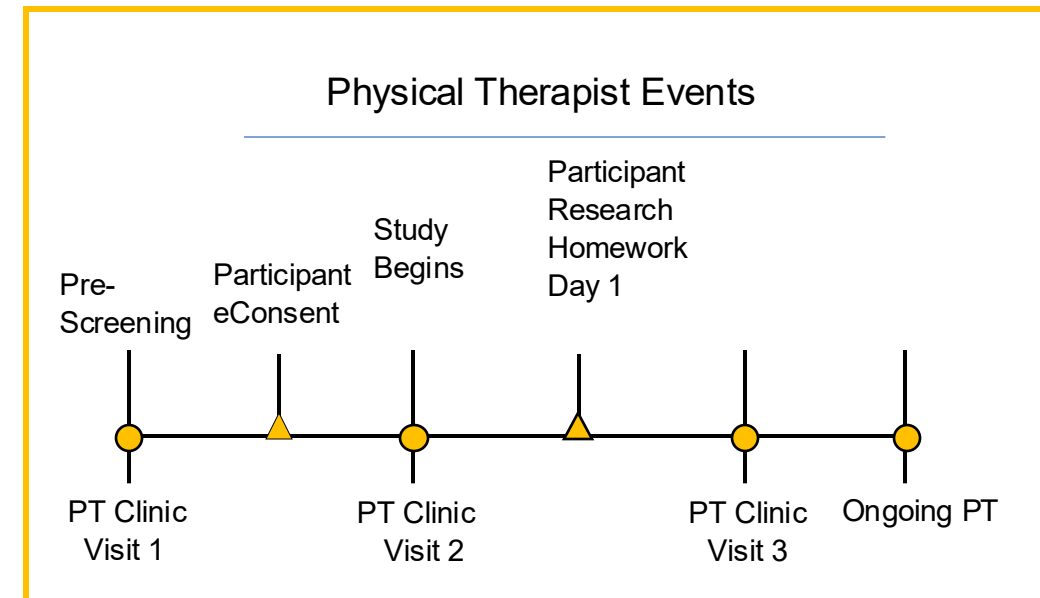
- Identify possible participant for the study
- Give brochure to interested patients
- If interested, have patient complete screening on tablet
- Patient will need to complete e-Consent on REDCap prior to Visit 2

PT Visit 2: e-Consent and Instruction

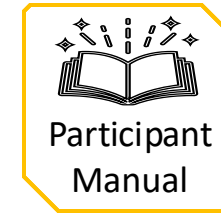
- Check on e-Consent completion, if not completed offer tablet to complete or patient declines
- If e-Consent completed, begin study
- Sit and Stand Importance
- Study Supplies given to patient (Manual, bag, pen)

PT Visit 3: Research Homework Check

- Check on completion of research homework
- If participant does not complete research homework, patient does not continue in the study
- Continue PT treatment per therapist



What do Patients/Participants do?



PT Visit 1

- Receive a brochure about the study
- Complete eligibility screen on Tablet in the clinic
- Results are emailed to patient, clinic representative and study team

Between PT Visit 1 and 2

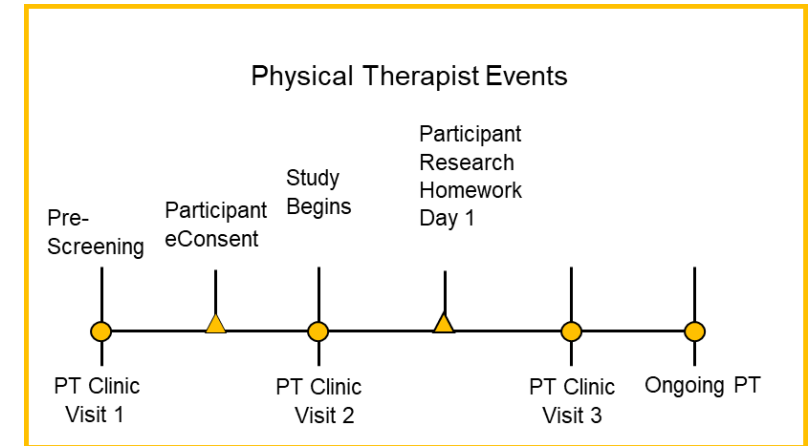
- eConsent via internet, must be done before study procedures can begin on PT Visit 2
- eConsent completion is emailed to clinic representative and study team

PT Visit 2

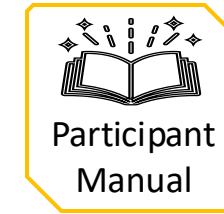
- Complete consent if not done before the PT Visit
- Begin study procedures

Between PT Visit 2 and 3 (up to 10 days)

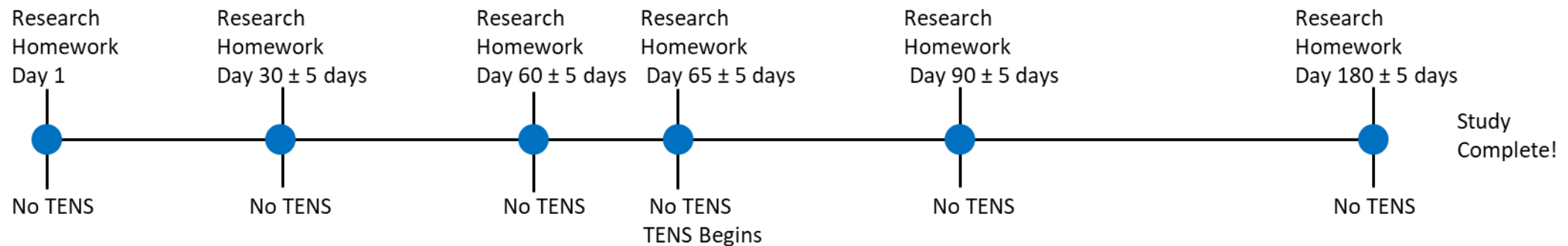
- Complete research homework day 1; same day or next day after Visit 2
- They will get email reminders from the study team



Participant Research Homework From Day 1 through 6 months



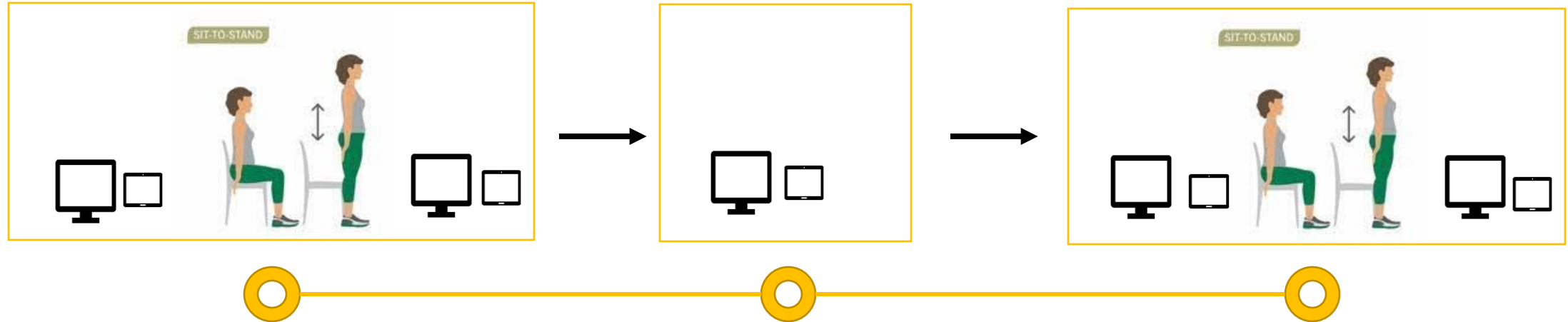
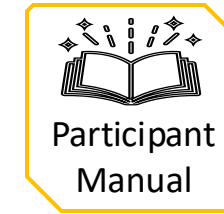
No TENS Participant Research Homework



Participants will be paid after each research homework session is completed, a total of \$200 and will keep the 2 Quell Flex TENS units

Study Activity Completion	Payment	Running Total
Home Activities Day 1	\$40	\$40
Home Activities Day 30	\$20	\$60
Home Activities Day 60	\$60	\$120
Home Activities Day 90	\$20	\$140
Home Activities Day 180	\$60	\$200
Total		\$200

Participant Research Homework: What do they do?



- Rate pain and fatigue at rest
- Perform sit and stand test
- Rate pain and fatigue at highest level during the sit and stand test

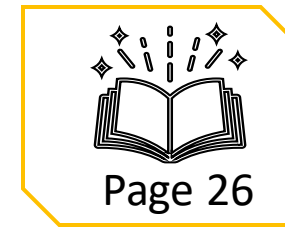
Complete surveys on REDCap,
approximately 30 minutes

- Rate pain and fatigue at rest
- Perform sit and stand test
- Rate pain and fatigue at highest level during the sit and stand test

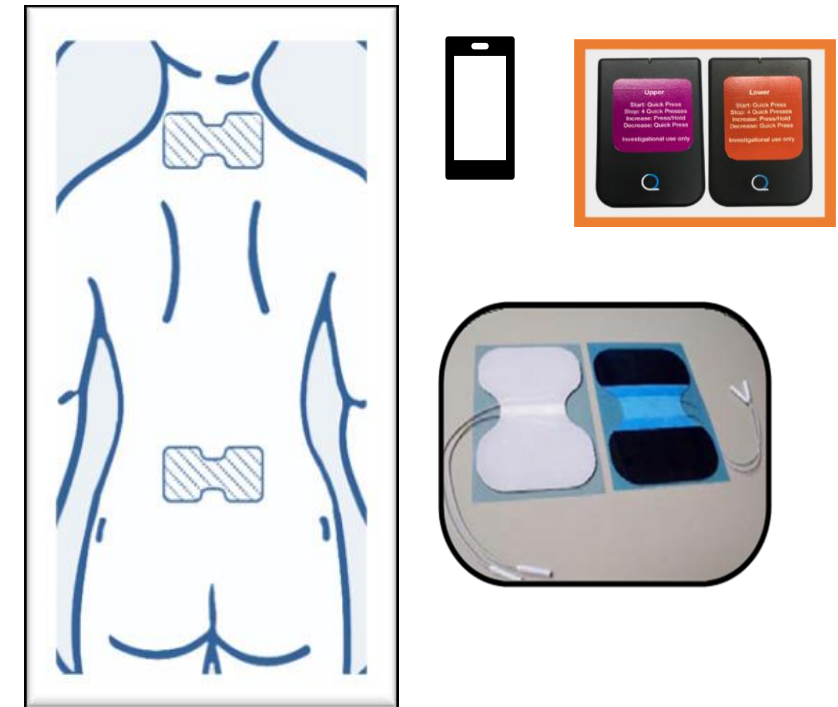
TENS Overview: No TENS Group

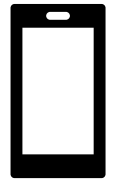
After Day 60 Research Homework

and a Study PT Telehealth Visit

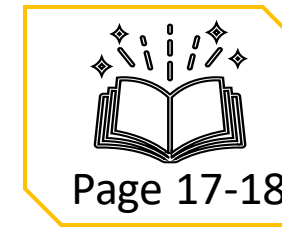


- Quell Flex Smartphone Application (App) Manual
- Quell Flex TENS units (2) and colored wires
 1. Upper back - purple
 2. Lower back - orange
- Butterfly electrodes (2) for upper back and lower back
- Duration: 30-minute sessions, 2 hours a day
- Intensity: Strong but comfortable
- Log in to quell flex smartphone app
 - at least 1 time a week*
- Wear TENS during activity in PT and at home





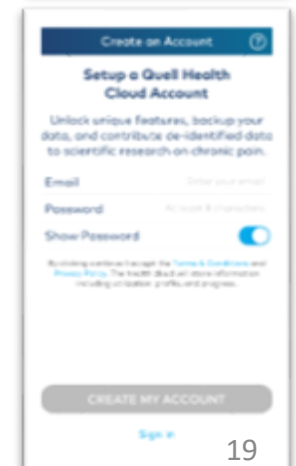
TENS Quick Start Guide: Quell Flex Smartphone App



Page 17-18

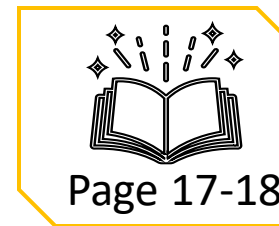


1. Using your mobile device or tablet, open the App Store or Google Play
2. Search “[Quell Flex](#)” by NeuroMetrix and download the app to your device.
3. Make sure Bluetooth is turned on and that your device is running iOS 10 or later, or Android 6 or later.
4. Launch the Quell Flex App and follow the step-by-step instruction within the app to pair both Quell TENS units.
5. Instructions within the app will guide you through two steps:
 - Set up your Health Cloud Account
 - Pair your devices with the phone
6. Creating a Health Cloud Account
 - For the email address, enter your unique study ID that you will receive from the research study team ([from site YY for example XXXX](#)) to TIPSYYXXXX@quellrelief.com.
 - Password: [dailytens](#)
7. You will pair both the “Upper” and “Lower” Quell TENS units. Once you enter the last two digits, the device will recognize your Quell Unit as either “Upper” or “Lower.”
8. **In order to capture your TENS use, we need you to open the app and make sure both units are paired within the Quell Flex App at least once a week.**





TENS Quick Start Guide: Begin a Treatment



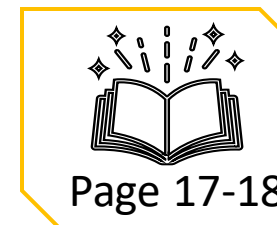
Page 17-18



1. Make sure the TENS units are OFF and fully charged.
2. The charger port is on the side of the unit. A full charge will take 1.5-2 hours.
3. Remove the unit from the wall charger.
4. Attach the lead wires to the electrodes.
5. Apply electrodes to clean dry skin.
6. Attach the color-coded lead wires to the TENS unit.
7. Turn the unit ON by pressing the blue button on the front.
8. The white light on top of the unit will flash (two quick flashes)
9. The stimulation will increase to a set level over two minutes.
10. Increase the intensity to be strong but comfortable by holding down the blue button.
11. After a few minutes, it may seem the stimulation has gone down. This is normal as your body gets used to the TENS.
12. You should turn up the intensity to keep it feeling strong, but comfortable.
13. Decrease the intensity by pressing and releasing the blue button.
14. The timer automatically sets for 60 minutes.
15. You may use the unit as much as desired.
16. For the study, we are asking you to wear TENS for 2 hours each day.
17. Wear the unit for a minimum of 30 minutes each session.
18. Try to wear your TENS when active.



TENS Quick Start Guide: End a Treatment & Resetting TENS Unit



Page 17-18



End a Treatment

1. Press and release the blue button 4 times in a row.
2. You may keep the electrodes in place for your next treatment.
3. Secure the units and wires in the pouch or a pocket.
4. If you see a flashing yellow light, it means there is a problem with connectivity. Turn the unit OFF. Check to make sure the wires are inserted into the unit as well as into the electrodes. Also, check to make sure your electrodes have good contact with your skin.
5. When you are finished with treatments for the day, remove your electrodes.
6. Find the white non-sticky section in the middle.
7. Gently pull to release the electrode. Hold your skin down next to the electrode as it releases.
8. Return the electrode to the plastic sheet and place in the zip lock bag.

Resetting the TENS Units

1. The Quell Flex TENS units automatically ramp up to the last intensity used. Clinics and participants may want to reset the units to the default of 5mA, the lowest setting.
2. While the TENS unit is off, press and hold the button for 2s (until rapid blinking of the white light is shown).
3. The unit then ramps up to 5mA [over 2 minutes] the first time you run a treatment.
4. Patients are then to increase to “strong but comfortable” for the session.
5. The next time they start a session, the unit ramps up to the last mA they utilized. They should further increase/decrease intensity to “strong but comfortable” for every session.
6. Remember, the number does not matter, the sensation of “as strong as possible while still being comfortable” is important. Intensity is linked to effectiveness!

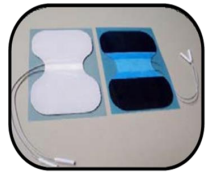




TENS Review



- The maximum intensity is 100 mA



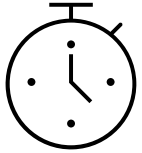
- Each subject receives 10 electrodes for a 2-month period. They are designed to last 10 - 14 days



- Trouble shooting and FAQ (TENS Booklet and No TENS clinician manual 18-19)



TENS Review



- Duration: 30-minute sessions with 2 hours per day



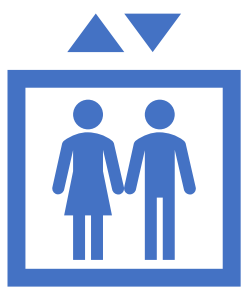
- Intensity: Strong but comfortable

QuellFlex

- Log in to quell app 1 time a week



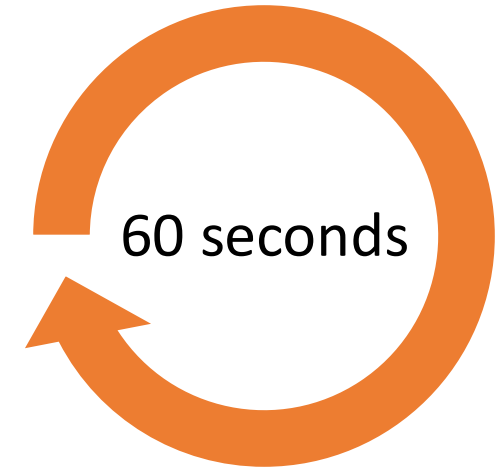
- Wear TENS during activity in PT and at home



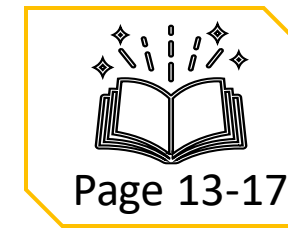
Return Demonstration: Elevator Pitch



- Most elevator pitches are less than 60 seconds
- Describe the study to a patient in a brief introduction. Some things to consider:
 - Effectiveness of TENS
 - Research study
 - 2 free TENS units and get paid
 - Interested?

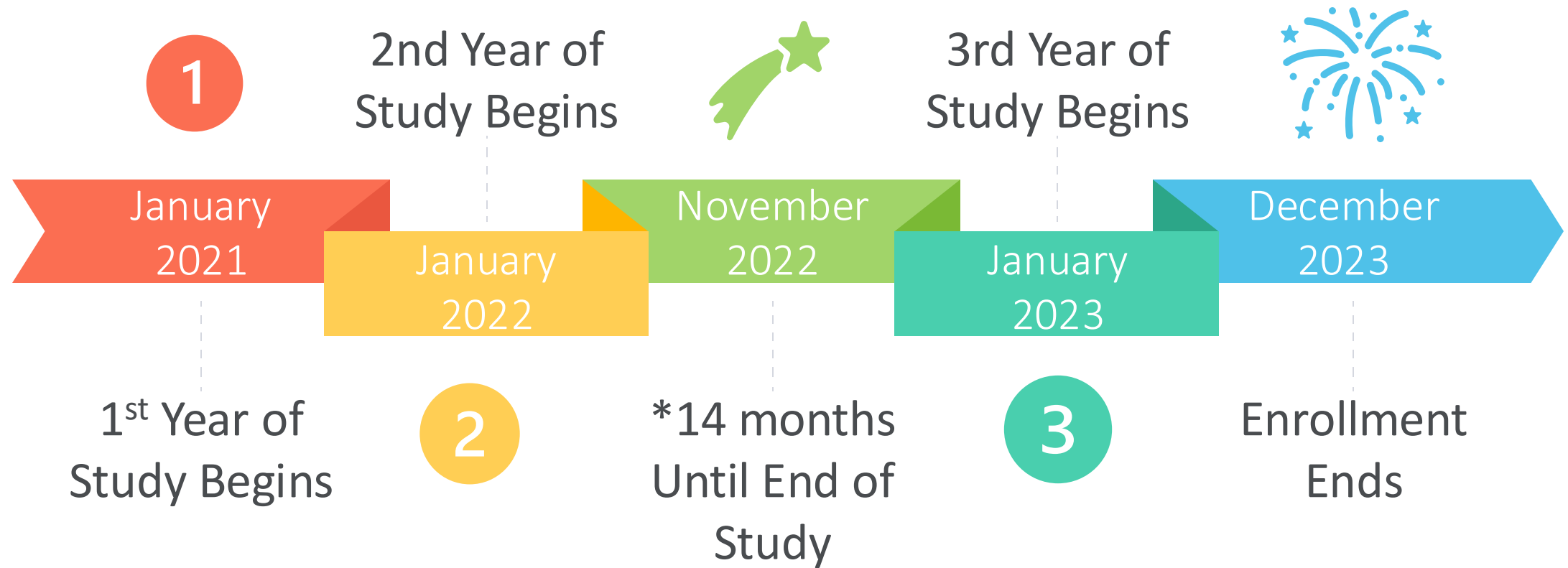


Return Demonstration: Role play with Scripts



- Use the scripts as examples of what to say in each situation.
- Practice these on each other to be prepared for potentially uncomfortable situations.
- Review: Remember to give clear instructions at each visit to ensure success of participants and make it clear of the consequences.
 - ☐ Visit 1
 - ☐ Visit 2
 - ☐ Visit 3
 - ☐ Post Visit 3

FM-TIPS Timeline





Clinic Planning and What Not to Do

Clinic Planning



- Screening all new patients with neck and back pain
- Best Practice
- TENS unit charging Plan
- iPad charging Plan
- Hanging the flyers in your clinic

What Not to Do:



- Clinicians need IRB approval prior to beginning the study
- Only trained clinicians can introduce the study or ask questions
 - Example: Front Office person or therapists who are not trained
- Study procedures can start after eConsent is signed by study staff – check clinic email



iPad Information

1



REDCap

REDCap – screening form
iPad password: 932020

2



Quell Flex App

3



Login

Our on-call study
team is
just a few
clicks away

Step 1. Log onto fmtips.org

FM-TIPS.org

Clinician page password: hcs2020



Report Folder

FM-TIPS
Fibromyalgia TENS in Physical Therapy Study

Study Contact Information

GENERAL HELP

Telephone: (319) 467-4203
Email: fmtips-studyteam@uiowa.edu

Need Immediate Help?
Monday - Friday
6am to 6 pm
Log into the clinician page on the fmtips.org website. Passcode fmtips.orghcs2020.
Click on the day/time or click on the pdf of the schedule for a study team member phone number.
Website: www.fmtips.org

Quell App ID:
This ID is created by combining:
TIPS (clinic 2-digit number)
(Patient Study 4-digit number)@
quellrelief.com
It will look like: TIPS991234@
quellrelief.com
App password: dailytens

Report Cover

FM-TIPS
Fibromyalgia TENS in Physical Therapy Study

Best Practices

Advertise FM-TIPS

- Place FM-TIPS brochures in the waiting room for patients to see and to ask about the study
- Hang FM-TIPS flyers in the clinic in multiple places: waiting room, restrooms, treatment rooms.
- Send letters about the study to providers in your area.

Best Practices

FM-TIPS iPad Cheat Sheet

FM-TIPS Contact Information

- Telephone: (319) 467-4203
- Email: fmtips-studyteam@uiowa.edu
- Website: www.fmtips.org

iPad Equipment

- iPad Number: CPH-UIOWA-30
- iPad Passcode: 932020
- Cable: Lightning to USB (connects the iPad to charging adaptor)
- AC Charging Adaptor (plugs into wall)

iPad Cheat Sheet

FM-TIPS
Fibromyalgia TENS in Physical Therapy Study

FM-TIPS TENS Unit Receipt

To: *Health System and Clinic Location*
Clinic Contact: *(Clinic Contact Name)*
Date of Receipt *(Date)*

☐ TENS Units

Case #	TENS Unit Number Upper	Check if present	TENS Unit Number Lower	Check if present

TENS Receipt Form

FM-TIPS
Fibromyalgia TENS in Physical Therapy Study

FM-TIPS TENS UNIT ACCOUNTABILITY LOG*

To: *Health System and Clinic Location*
Clinic Contact: *(Clinic Contact Name)*
Telephone: *(Telephone)*

Date Received	Case #	Date Dispensed*	Dispensed To (Subject Initials/ID#)	Quell Login ID **	Tracking Number	Date Returned to University of Iowa

TENS Accountability Log



FM-TIPS

Fibromyalgia TENS In
Physical Therapy Study

THE UNIVERSITY
OF IOWA

VANDERBILT UNIVERSITY
MEDICAL CENTER

FM-TIPS Contact and Study Information



Email: FMTips-StudyTeam@uiowa.edu

Phone: 319-467-4203

iPad password: **932020**

Website: www.fmtips.org

Steps to log into clinician page on back of card

Clinician page password: ***fmtips@hcs2020***

FM-TIPS Study Team Representatives

APTSM:

Barb Van Gorp

barbara-vangorp@uiowa.edu

Genesis PT:

Dana Dailey

dana-dailey@uiowa.edu

RVPT:

Carol Vance

carol-vance@uiowa.edu

BST:

Dana Dailey

dana-dailey@uiowa.edu

Kepros PT:

Liz Johnson

elizabeth.m.johnson@vumc.org

UIC PT:

Andrew Post

andrew-post@uiowa.edu

BST:

Carol Vance

carol-vance@uiowa.edu

RVPT:

Dana Dailey

dana-dailey@uiowa.edu

Clinician Login: Fmtips.org

CLINICIAN LOGIN AND IMMEDIATE HELP CONTACTS



Login

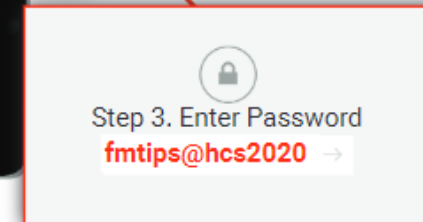
Our on-call study team is just a few clicks away

Step 1. Log onto fmtips.org



LOG IN

Step 2. Click on the "Log in" button



Step 3. Enter Password

fmtips@hcs2020 →



DOWNLOAD PDF
VERSION

Step 4. Download PDF

the study team to let them know
from the study team before

OR

[Friday 6am - 8am](#)

[Friday 8am - 3pm](#)

[Friday 3pm - 6pm](#)

If using a cell phone click on hyperlink with corresponding day/time for automatic call

Continuing Education

Recordings Available

- Dr. Sluka - TENS
- Dr. Crofford - FM
- Dr. Crofford – Pharmacology and FM
- Dr Archer – Psychologically Informed PT
- Movement Evoked Pain Dr. Chimenti and Dr. Post
- Dr. Sluka - Exercise as Analgesia



Upcoming

May – Dr. Martin, Implicit Bias

Provider Follow Up Letter & Brochure



FM-TIPS

Fibromyalgia TENS in
Physical Therapy Study
www.fmtips.org

University of Iowa
Department of Physical Therapy & Rehabilitation Science

Roy J. and Lucille A.
Carver College of Medicine
1-252 Medical Education Building
500 Newton Road, Iowa City, IA 52242-1190
319-335-9791 Tel 319-335-9707 Fax

[Date]

[Provider Name and Credentials],

[Provider Address]

Re: Referrals for the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

We are excited to be a part of FM-TIPS, a NIH funded study, with the University of Iowa and Vanderbilt University Medical Center. This study is recruiting patients through December, 2023.

What is the study about?

We are looking at the use of TENS for pain and function with individuals who have fibromyalgia and chronic spine pain.

Who can participate?

Adults who are 18 years or older who have fibromyalgia and neck or back pain

What do patients do in the study?

- Physical therapy as usual
- Receive and wear 2 TENS units up to 2 hours a day
- Complete surveys at home (5 times over 6 months) and receive payment

If you have patients with fibromyalgia that might benefit from the study, please consider referring to [Clinic Name] for physical therapy. Please reach out to the clinics or the study team with questions. We appreciate your support for this important study.

Kathleen A. Sluka

Kathleen A. Sluka, PT, PhD
Co-Primary Investigator
University of Iowa
FM-TIPS

Leslie J. Crofford

Leslie J. Crofford, MD
Co-Primary Investigator
Vanderbilt University Medical Center
FM-TIPS



Front

Do you have neck or back pain?

Do you have fibromyalgia?

Interested? Ask your Physical Therapist about getting involved

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

Back

Who Can Participate?

Adults who are 18 years or older who have fibromyalgia and neck or back pain

What Will I Do in the Study?

- Receive and wear 2 TENS units
- Physical therapy
- Complete surveys at home (5 times over 6 months)
- Receive payment



How Long Will I Be in the Study?

About 6 months

What is the Study About?

We want to know if use of TENS reduces pain and improves mobility for individuals with fibromyalgia and chronic spine pain





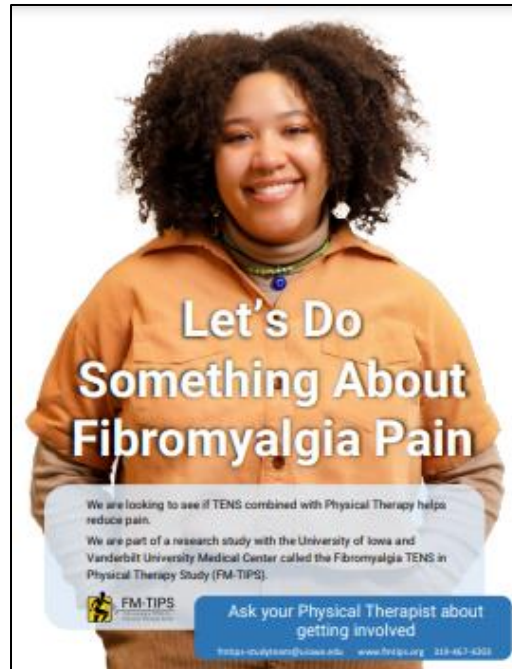
Let's Do Something About Fibromyalgia Pain

ASK YOUR PHYSICAL THERAPIST ABOUT GETTING INVOLVED

We are looking to see if TENS combined with Physical Therapy helps reduce pain.

We are part of a research study with the University of Iowa and Vanderbilt University Medical Center called the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

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



Let's Do Something About Fibromyalgia Pain

We are looking to see if TENS combined with Physical Therapy helps reduce pain.

We are part of a research study with the University of Iowa and Vanderbilt University Medical Center called the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

 **Ask your Physical Therapist about getting involved**

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

Let's Do Something About Fibromyalgia Pain



We are looking to see if TENS combined with Physical Therapy helps reduce pain.

We are part of a research study with the University of Iowa and Vanderbilt University Medical Center called the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

Ask your Physical Therapist about getting involved

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

Let's Do Something About Fibromyalgia Pain



ASK YOUR PHYSICAL THERAPIST ABOUT GETTING INVOLVED

We are looking to see if TENS combined with Physical Therapy helps reduce pain.

We are part of a research study with the University of Iowa and Vanderbilt University Medical Center called the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

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

Clinic Flyers

Public Flyer

Can be used at community spaces, provider offices, etc.

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

fmtps-studyteam@uiowa.edu



www.fmtps.org 319-467-4203





Questions, Discussion, Next Steps?



- Questions?



- Discussion



- Next Steps
 - IRB Approval Notification
 - Ready, Set, Go!



FM-TIPS

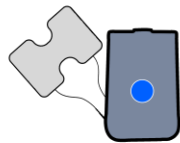
*Fibromyalgia TENS In
Physical Therapy Study*

Contact information:

Telephone: (319) 467-4203

Email: fmtips-studyteam@uiowa.edu

Website: www.fmtips.org



TENS Evidence List



Dailey DL, Vance CGT, Rakel BA, Zimmerman MB, Embree J, Merriwether EN, Geasland KM, Chimenti R, Williams JM, Golchha M, Crofford LJ, Sluka KA. Transcutaneous Electrical Nerve Stimulation Reduces Movement-Evoked Pain and Fatigue: A Randomized, Controlled Trial. *Arthritis Rheumatol*. 2020 May;72(5):824-836. doi: 10.1002/art.41170. Epub 2020 Mar 18. PMID: 31738014; PMCID: PMC7188591.

Dailey DL, Rakel BA, Vance CGT, Liebano RE, Amrit AS, Bush HM, Lee KS, Lee JE, Sluka KA. Transcutaneous electrical nerve stimulation reduces pain, fatigue and hyperalgesia while restoring central inhibition in primary fibromyalgia. *Pain*. 2013 Nov;154(11):2554-2562. doi: 10.1016/j.pain.2013.07.043. Epub 2013 Jul 27. PMID: 23900134; PMCID: PMC3972497.

Johnson MI. Resolving Long-Standing Uncertainty about the Clinical Efficacy of Transcutaneous Electrical Nerve Stimulation (TENS) to Relieve Pain: A Comprehensive Review of Factors Influencing Outcome. *Medicina (Kaunas)*. 2021 Apr 14;57(4):378. doi: 10.3390/medicina57040378. PMID: 33919821; PMCID: PMC8070828.

Moran F, Leonard T, Hawthorne S, Hughes CM, McCrum-Gardner E, Johnson MI, Rakel BA, Sluka KA, Walsh DM. Hypoalgesia in response to transcutaneous electrical nerve stimulation (TENS) depends on stimulation intensity. *J Pain*. 2011 Aug;12(8):929-35. doi: 10.1016/j.jpain.2011.02.352. Epub 2011 Apr 9. PMID: 21481649.

Paley CA, Wittkopf PG, Jones G, Johnson MI. Does TENS Reduce the Intensity of Acute and Chronic Pain? A Comprehensive Appraisal of the Characteristics and Outcomes of 169 Reviews and 49 Meta-Analyses. *Medicina (Kaunas)*. 2021 Oct 4;57(10):1060. doi: 10.3390/medicina57101060. PMID: 34684097; PMCID: PMC8539683

Vance CGT, Zimmerman MB, Dailey DL, Rakel BA, Geasland KM, Chimenti RL, Williams JM, Golchha M, Crofford LJ, Sluka KA. Reduction in movement-evoked pain and fatigue during initial 30-minute transcutaneous electrical nerve stimulation treatment predicts transcutaneous electrical nerve stimulation responders in women with fibromyalgia. *Pain*. 2021 May 1;162(5):1545-1555. doi: 10.1097/j.pain.0000000000002144. PMID: 33230010; PMCID: PMC8049882.

Vance CG, Chimenti RL, Dailey DL, Hadlandsmayth K, Zimmerman MB, Geasland KM, Williams JM, Merriwether EN, Alemo Munters L, Rakel BA, Crofford LJ, Sluka KA. Development of a method to maximize the transcutaneous electrical nerve stimulation intensity in women with fibromyalgia. *J Pain Res*. 2018 Oct 10;11:2269-2278. doi: 10.2147/JPR.S168297. PMID: 30349353; PMCID: PMC6188186.

Vance CG, Dailey DL, Rakel BA, Sluka KA. Using TENS for pain control: the state of the evidence. *Pain Manag*. 2014 May;4(3):197-209. doi: 10.2217/pmt.14.13. PMID: 24953072; PMCID: PMC4186747.

Vance CG, Chimenti RL, Dailey DL, Hadlandsmayth K, Zimmerman MB, Geasland KM, Williams JM, Merriwether EN, Alemo Munters L, Rakel BA, Crofford LJ, Sluka KA. Development of a method to maximize the transcutaneous electrical nerve stimulation intensity in women with fibromyalgia. *J Pain Res*. 2018 Oct 10;11:2269-2278. doi: 10.2147/JPR.S168297. PMID: 30349353; PMCID: PMC6188186.

Sluka KA, Bjordal JM, Marchand S, Rakel BA. What makes transcutaneous electrical nerve stimulation work? Making sense of the mixed results in the clinical literature. *Phys Ther*. 2013 Oct;93(10):1397-402. doi: 10.2522/ptj.20120281. Epub 2013 May 2. PMID: 23641031; PMCID: PMC3788712.



FM-TIPS

*Fibromyalgia TENS In
Physical Therapy Study*

Onsite Clinician Training TENS Clinic

University of Iowa

Vanderbilt University Medical Center



Introductions and Importance of FM-TIPS

Introductions



- What is a pragmatic trial?
 - Real world setting: OP PT Clinics
- This is an important trial – robust trial of nonpharmacological treatment for pain
- Integrated team of clinicians and scientists
- High impact for PT knowledge base and foundation for future PT clinical research
- Pragmatic trials are the future



Plan for Today



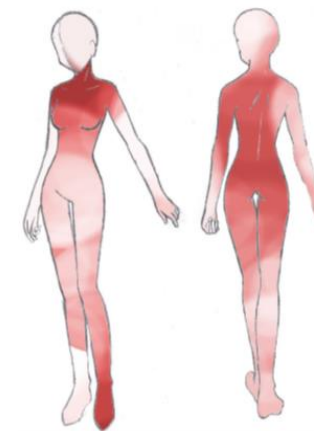
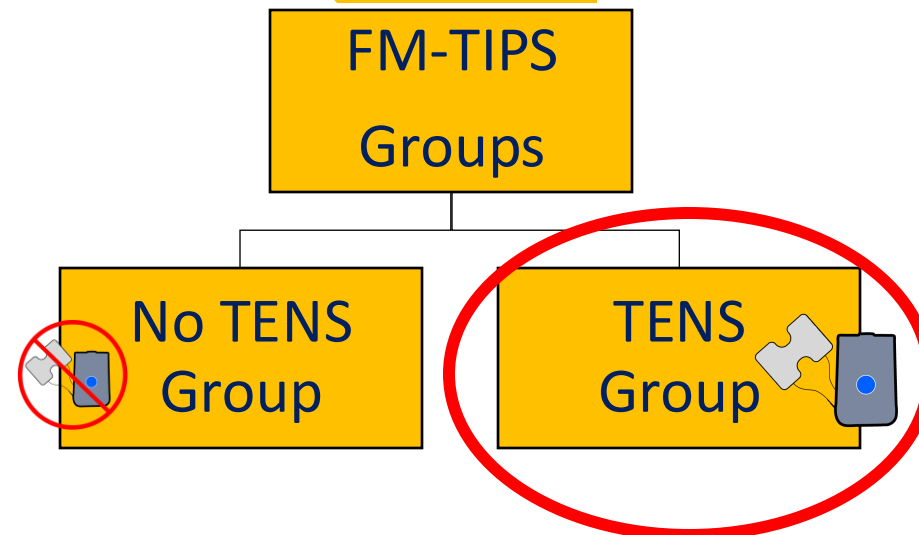
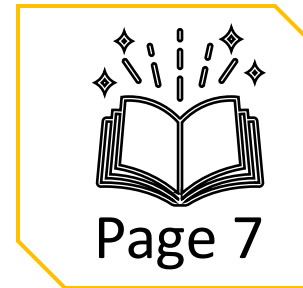
- Introduction
- Importance of FM-TIPS
- Goals for FM-TIPS
- TENS Evidence
- Materials
- Highlight Participant Activities and PT critical decisions
- Quell Flex TENS Introduction
- Return Demonstration
- Role Play with Scripts
- Clinic Planning for Study Activities
- What Not to Do
- Questions and discussion
- Next Steps

FM-TIPS Goals

1. Demonstrate the feasibility of adding TENS to usual physical therapy treatment of patients with FM in a real-world PT practice setting
2. Determine if the addition of TENS to standard PT for FM reduces pain, increases adherence to PT and allows patients with FM to reach their specific functional goals with less drug use

Last Enrollment:
December 2023

December 2023						
Su	M	T	W	Th	F	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						



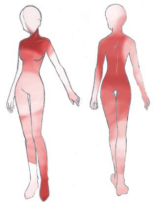
1/month



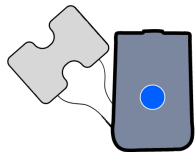
Why TENS?



- Exercise is a recommended intervention for patients with fibromyalgia



- Fibromyalgia patients have increased pain with exercise



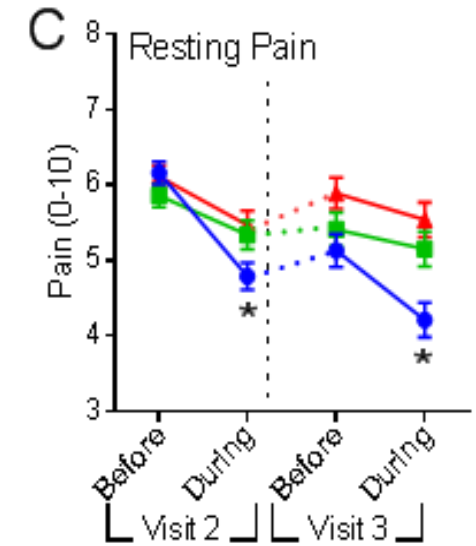
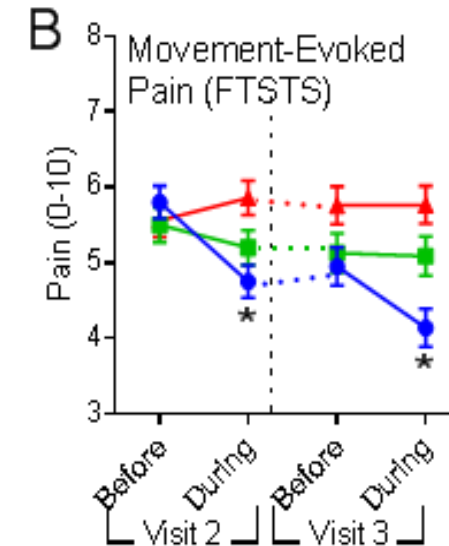
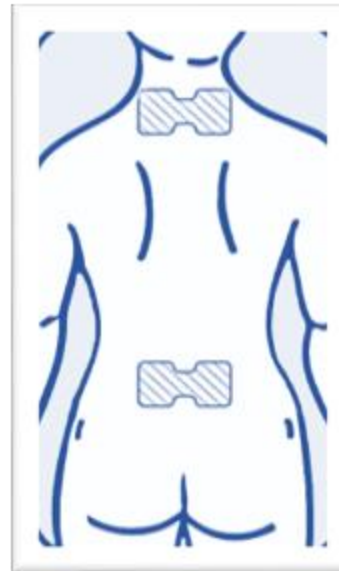
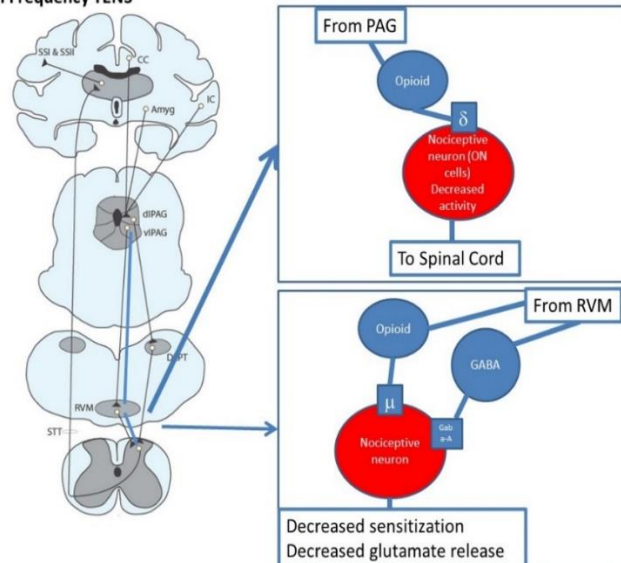
- TENS reduces pain and fatigue with movement!



Review of TENS Evidence

- Parameters are important for success – intensity, frequency, duration, and activity
- Discussion about TENS evidence
- Reference List (last slide) If you would like a copy of a paper, please us know.

High Frequency TENS

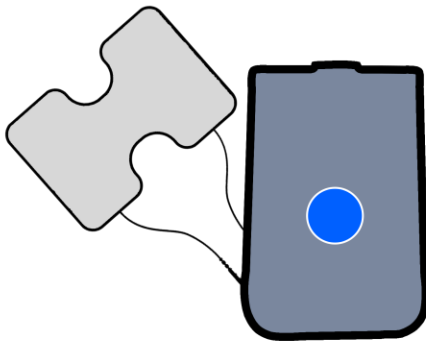




Study Materials: TENS Group

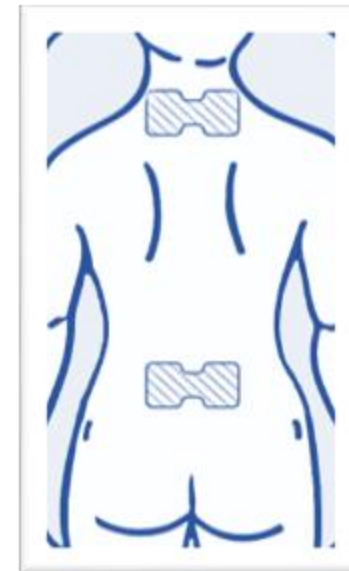
Clinician Materials

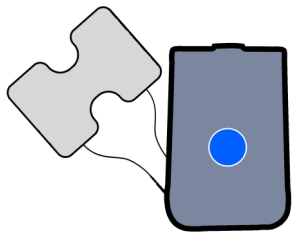
- TENS Clinician Manual
- TENS Electrodes for practicing
- FM-TIPS Pen
- Contact Card



Participant Materials in the Bag

- TENS Participant Manual
- Study Bag, Pen
- Quell Flex TENS Units
- 10 butterfly electrodes





Study Materials: TENS Group



Clinic Materials

- Flyers, Brochures, Pens
- TENS Clinician and Participant Manual
- Clinic Quell Flex TENS Units (2) and QuickStart Guide
- Quell Flex TENS and App Booklets
- Laminated Forms (2 sets)
- iPad
- Report Folder
 - Report Cover with clinic number
 - iPad Cheat Sheet
 - Best Practices
 - TENS Receipt Form
 - TENS Accountability Log

Clinic Plans for Success!!!

- Post Flyers in your clinic
- Place brochures where you can access them easily
- Plan to identify possible participants on schedule or folder – weekly is best
- Screening plan for all new patients with neck and back pain (best practices)
- iPad charging
- TENS unit charging (charge lasts 2 weeks)
- Storage plan for participant bags

Identify Possible Participants



Therapist Identifies:

- Neck pain and fibromyalgia
- Back pain and fibromyalgia
- Fibromyalgia
- Stable medically or psychologically

Criteria covered in the iPad Screen

Inclusion Criteria

- Age 18 or above
- Clinician diagnosis of fibromyalgia (patient reported)
- Able to provide informed consent
- Fluent in reading English
- Willing to use TENS

Exclusion Criteria

- *Clinically unstable medical or psychiatric issues*
- Currently enrolled in another pain control study
- Use of TENS within the last 30 days
- Contraindications to TENS:
 - Pacemaker, defibrillator, implanted neurostimulator or implanted device, Epilepsy, Currently pregnant or plan to become pregnant in the next 6 months
- Allergic reaction to patches with gel

iPad Screening p.1



REDCap

Click on the
REDCap Icon on
the iPad when
you are ready
to have your
patient screen.

Please feel free to ask questions at any time by contacting our team. Here are a few ways to contact us:

- Telephone: 319-467-4203
- Email: fmtips-icf@uiowa.edu
- Website: fmtips.org

If you are interested in participating in the FM-TIPS study, the next step is to answer a few screening questions to see if you qualify for FM-TIPS.

I have read the above information and would like to complete the screening questions.

* must provide value

☐ No ☐ Yes

First name:

* must provide value



Last name:

* must provide value



Phone Number:



Study notifications and communication are through email,
phone and text messages. If you would like to
opt out of the text messaging please check the box to the right.



☐ Click here to opt out

iPad Screening p.2

Site: * must provide value	(H)	
Email address (Used for study access and communication) * must provide value	(H)	
	No	Yes
Are you 18 years of age or older? * must provide value	(H) ☐	☐
Have you been told you have fibromyalgia by a physician or other clinician? * must provide value	(H) ☐	☐
Are you currently starting physical therapy for neck pain or back pain or fibromyalgia? * must provide value	(H) ☐	☐
Are you able to read English well? * must provide value	(H) ☐	☐
Are you willing to wear a TENS unit and electrodes for your neck and back? * must provide value	(H) ☐	☐

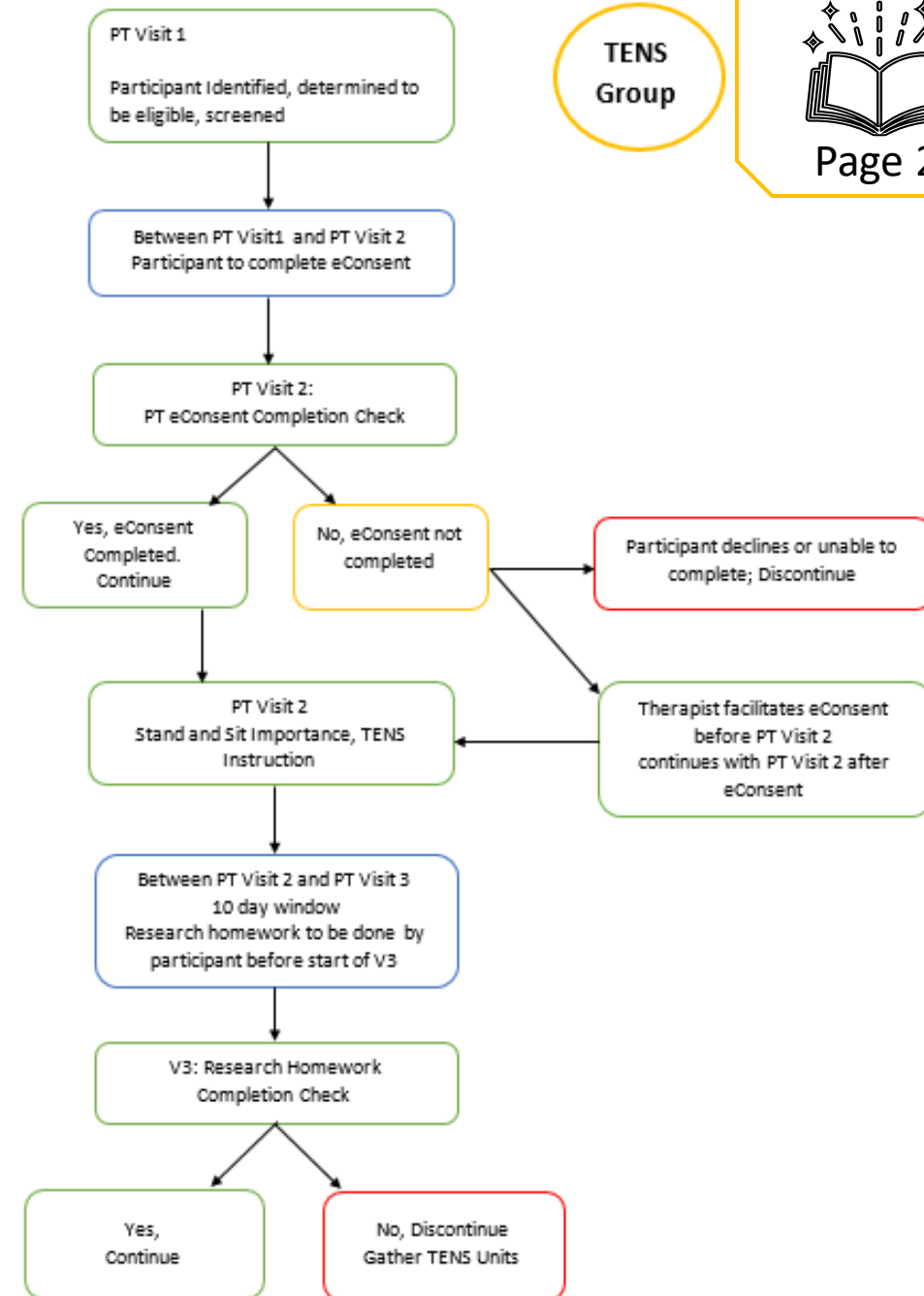
iPad Screening p.3

	No	Yes
Do you have an implanted device that is controlled electronically such as a pacemaker, defibrillator, or neurostimulator? * must provide value	☐	☐
Are you currently enrolled in another research study for pain control? * must provide value	☐	☐
Have you used TENS in the last 30 days? * must provide value	☐	☐
Do you have epilepsy? * must provide value	☐	☐
Are you being treated for active cancer? * must provide value	☐	☐
Are you currently pregnant or planning to become pregnant in the next 6 months? * must provide value	☐	☐
Do you have an allergic reaction to gel pads on your skin - similar to the gel on an EKG patch? * must provide value	☐	☐
Thank you for taking the time to answer the FM-TIPS screening questions. Based on your answers, we are sorry, but you do not qualify to participate in the study. Please feel free to ask questions by contacting our research study team. Here are a few ways to contact us: • Telephone: 319.382.0834 • Email: fmtipsstudyteam@gmail.com • Website: fmtips.org You will also receive an email with this information		
Id field		View equation
Form Status		
Complete?	Incomplete	



PT Decision Points

- **PT Visit 1:**
 - Identify possible participant
 - Patient Specific Functional Scale (PSFS)
 - Pre-enrollment screen on tablet
- **PT Visit 2:**
 - eConsent Check
 - TENS Instruction
 - Sit and Stand Importance
- **PT Visit 3:**
 - Research Homework Day 1 Check



TENS
Group



Page 25



Events in PT Visit 1 to PT Visit 3

Page 8, 24



PT Visit 1: Eligibility and study introduction

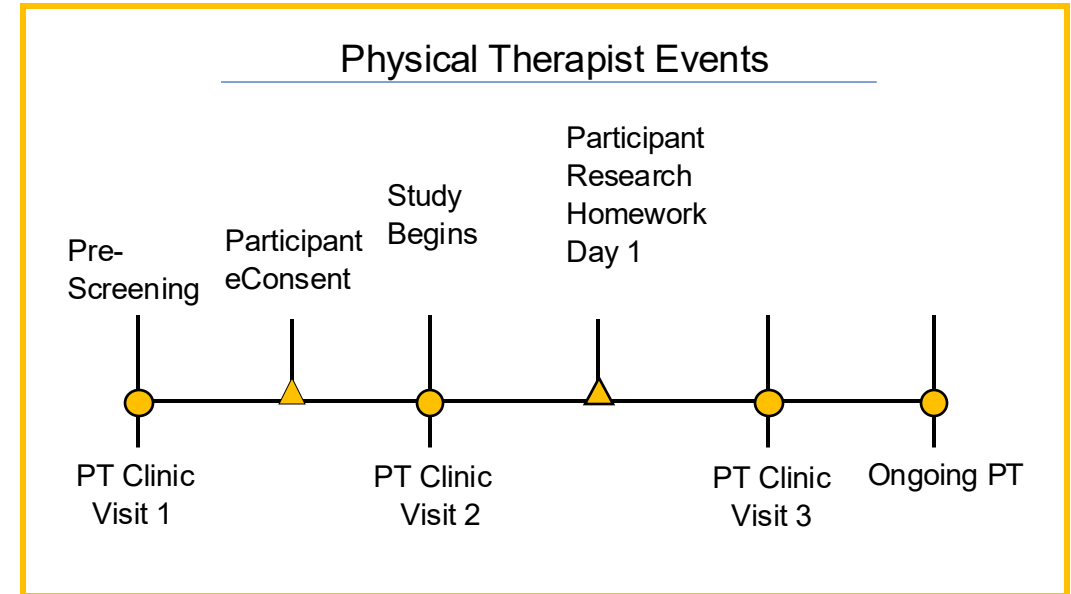
- Complete Patient Specific Functional Scale during evaluation
- Identify possible participants for the study
- Give brochure to interested patients
- If interested, have patient complete screening on tablet
- Patient will need to complete e-Consent on REDCap prior to Visit 2

PT Visit 2: e-Consent and Instruction

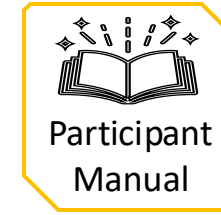
- Check on e-Consent completion, if not completed offer tablet or patient declines
- If e-Consent completed, begin study
- Sit and Stand Importance
- TENS instruction
- Study Supplies given to patient

PT Visit 3: Home Activity Check

- Check on completion of research homework
- Apply TENS during activity
- Complete PT treatment per therapist
- If participant does not complete research homework, patient returns TENS units to clinic



What do Patients/Participants do?



PT Visit 1

- Complete the Patient Specific Functional Scale with PT
- Receive a brochure about the study
- Complete eligibility screen on Tablet in the clinic
- Results are emailed to patient, clinic representative and study team

Between PT Visit 1 and 2

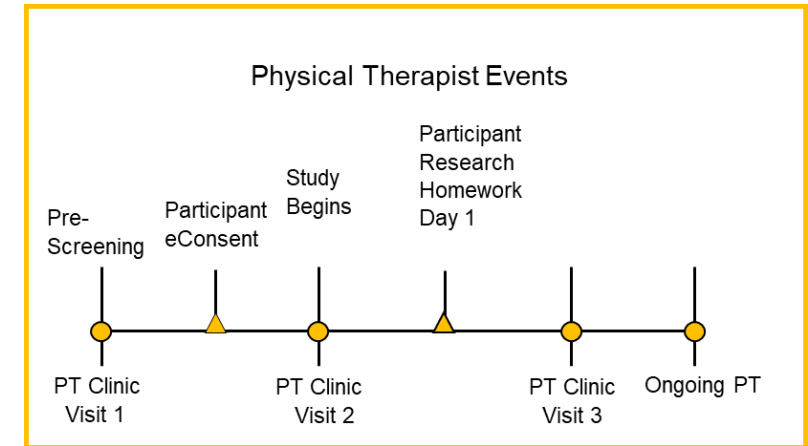
- eConsent via internet, must be done before study procedures can begin on PT Visit 2
- eConsent completion is emailed to clinic representative and study team

PT Visit 2

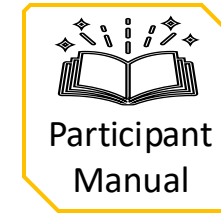
- Complete consent if not done before the PT Visit
- Begin study procedures – TENS instruction

Between PT Visit 2 and 3 (up to 10 days)

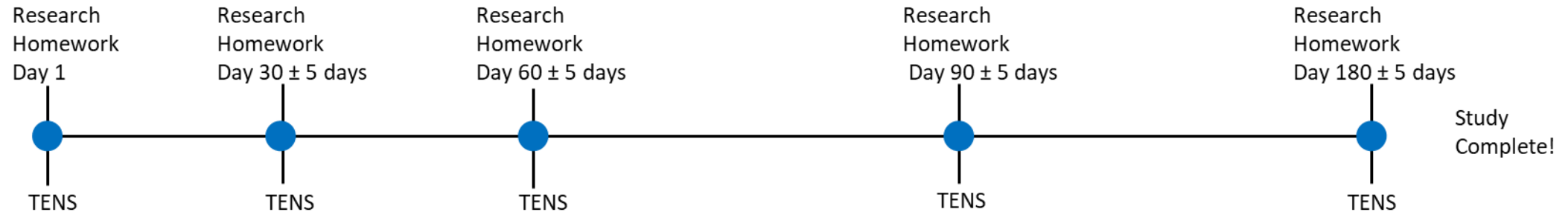
- Complete research homework day 1; same day or next day after Visit 2
- They will get email reminders from the study team



Participant Research Homework From Day 1 through 6 months



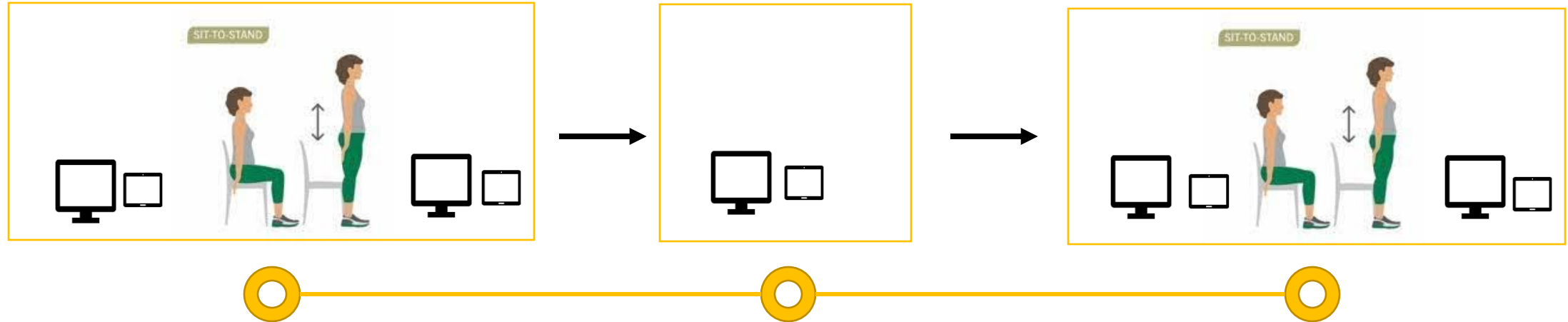
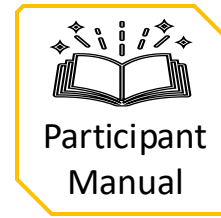
TENS Participant Research Homework



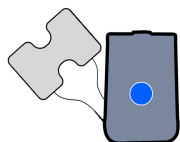
Participants will be paid after each research homework session is completed, a total of \$200 and will keep the 2 Quell Flex TENS units

Study Activity Completion	Payment	Running Total
Home Activities Day 1	\$40	\$40
Home Activities Day 30	\$20	\$60
Home Activities Day 60	\$60	\$120
Home Activities Day 90	\$20	\$140
Home Activities Day 180	\$60	\$200
Total		\$200

Participant Research Homework: What do they do?

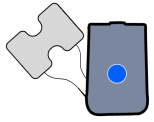


- Rate pain and fatigue at rest
- Perform sit and stand test
- Rate pain and fatigue at highest level during the Sit and Stand Test
- **Begin TENS for 30 minutes**

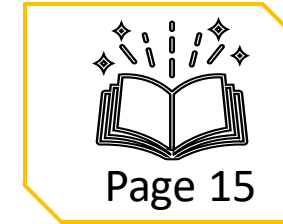


Complete surveys on REDCap,
approximately 30 minutes

- Rate pain and fatigue at rest
- Perform sit and stand test
- Rate pain and fatigue at highest level during the Sit and Stand Test



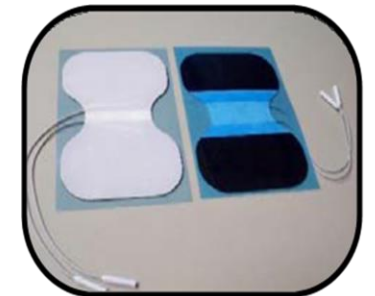
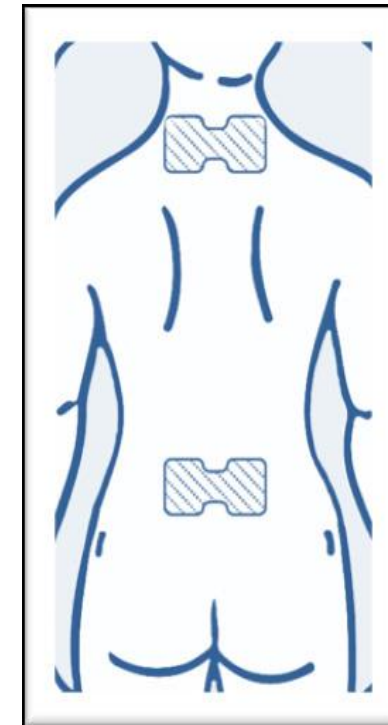
TENS Overview: TENS Group

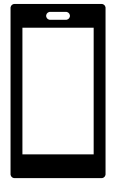


Page 15

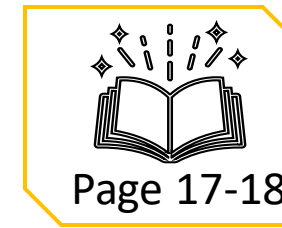


- Quell Flex Smartphone Application (App) Manual
- Quell Flex TENS units (2) and colored wires
 1. Upper back - purple
 2. Lower back - orange
- Butterfly electrodes (2) for upper back and lower back
- Duration: 30-minute sessions, 2 hours a day
- Intensity: Strong but comfortable
- Log in to quell flex smartphone app
at least 1 time a week
- Wear TENS during activity in PT and at home





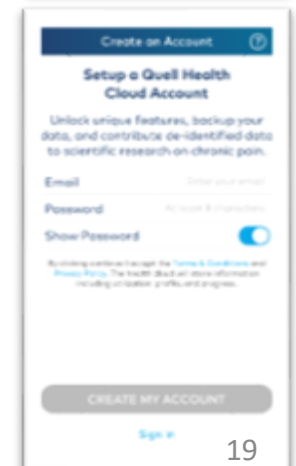
TENS Quick Start Guide: Quell Flex Smartphone App



Page 17-18

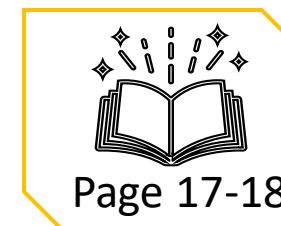


1. Using your mobile device or tablet, open the App Store or Google Play
2. Search “[Quell Flex](#)” by NeuroMetrix and download the app to your device.
3. Make sure Bluetooth is turned on and that your device is running iOS 10 or later, or Android 6 or later.
4. Launch the Quell Flex App and follow the step-by-step instruction within the app to pair both Quell TENS units.
5. Instructions within the app will guide you through two steps:
 - Set up your Health Cloud Account
 - Pair your devices with the phone
6. Creating a Health Cloud Account
 - For the email address, enter your unique study ID that you will receive from the research study team ([from site YY for example XXXX](#)) to TIPSYYXXXX@quellrelief.com.
 - Password: [dailytens](#)
7. You will pair both the “Upper” and “Lower” Quell TENS units. Once you enter the last two digits, the device will recognize your Quell Unit as either “Upper” or “Lower.”
8. **In order to capture your TENS use, we need you to open the app and make sure both units are paired within the Quell Flex App at least once a week.**





TENS Quick Start Guide: Begin a Treatment



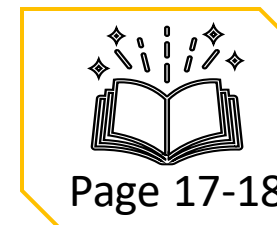
Page 17-18



1. Make sure the TENS units are OFF and fully charged.
2. The charger port is on the side of the unit. A full charge will take 1.5-2 hours.
3. Remove the unit from the wall charger.
4. Attach the lead wires to the electrodes.
5. Apply electrodes to clean dry skin.
6. Attach the color-coded lead wires to the TENS unit.
7. Turn the unit ON by pressing the blue button on the front.
8. The white light on top of the unit will flash (two quick flashes)
9. The stimulation will increase to a set level over two minutes.
10. Increase the intensity to be strong but comfortable by holding down the blue button.
11. After a few minutes, it may seem the stimulation has gone down. This is normal as your body gets used to the TENS.
12. You should turn up the intensity to keep it feeling strong, but comfortable.
13. Decrease the intensity by pressing and releasing the blue button.
14. The timer automatically sets for 60 minutes.
15. You may use the unit as much as desired.
16. For the study, we are asking you to wear TENS for 2 hours each day.
17. Wear the unit for a minimum of 30 minutes each session.
18. Try to wear your TENS when active.



TENS Quick Start Guide: End a Treatment & Resetting TENS Unit



Page 17-18



End a Treatment

1. Press and release the blue button 4 times in a row.
2. You may keep the electrodes in place for your next treatment.
3. Secure the units and wires in the pouch or a pocket.
4. If you see a flashing yellow light, it means there is a problem with connectivity. Turn the unit OFF. Check to make sure the wires are inserted into the unit as well as into the electrodes. Also, check to make sure your electrodes have good contact with your skin.
5. When you are finished with treatments for the day, remove your electrodes.
6. Find the white non-sticky section in the middle.
7. Gently pull to release the electrode. Hold your skin down next to the electrode as it releases.
8. Return the electrode to the plastic sheet and place in the zip lock bag.

Resetting the TENS Units

1. The Quell Flex TENS units automatically ramp up to the last intensity used. Clinics and participants may want to reset the units to the default of 5mA, the lowest setting.
2. While the TENS unit is off, press and hold the button for 2s (until rapid blinking of the white light is shown).
3. The unit then ramps up to 5mA [over 2 minutes] the first time you run a treatment.
4. Patients are then to increase to “strong but comfortable” for the session.
5. The next time they start a session, the unit ramps up to the last mA they utilized. They should further increase/decrease intensity to “strong but comfortable” for every session.
6. Remember, the number does not matter, the sensation of “as strong as possible while still being comfortable” is important. Intensity is linked to effectiveness!

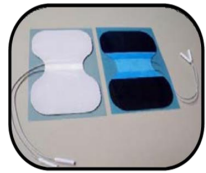




TENS Review



- The maximum intensity is 100 mA



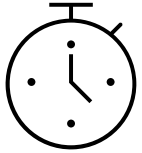
- Each subject receives 10 electrodes for a 2-month period. They are designed to last 10 - 14 days



- Trouble shooting and FAQ (TENS Clinician manual pp.18-19 and TENS Booklet)



TENS Review



- Duration: 30-minute sessions with 2 hours per day



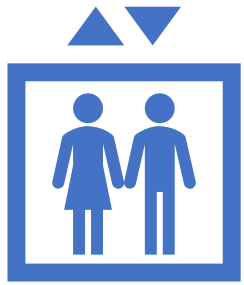
- Intensity: Strong but comfortable



- Log in to quell flex smartphone app 1 time a week



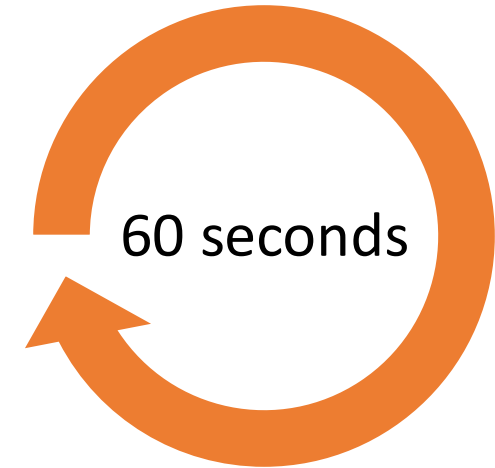
- Wear TENS during activity in PT and at home



Return Demonstration: Elevator Pitch



- Most elevator pitches are less than 60 seconds
- Describe the study to a patient in a brief introduction. Some things to consider:
 - Effectiveness of TENS
 - Research study
 - 2 free TENS units and get paid
 - Interested?



Return Demonstration: Role play with Scripts



- Use the scripts as examples of what to say in each situation.



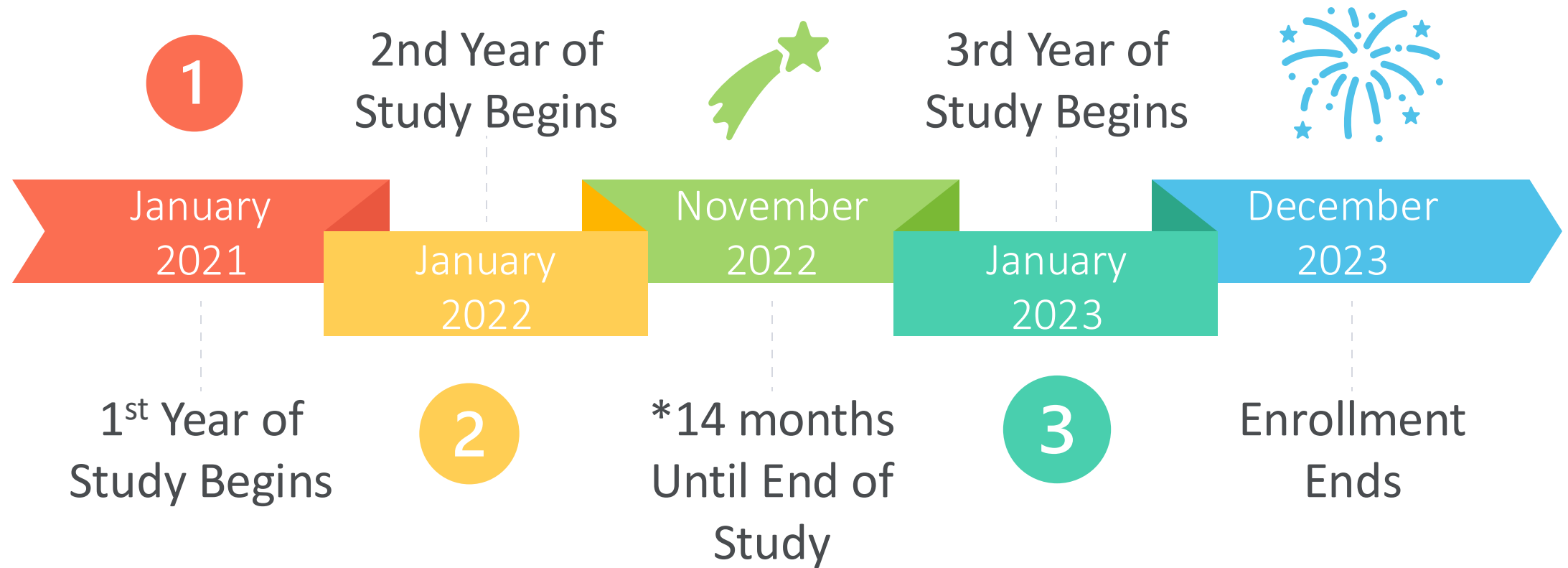
- Practice these on each other to be prepared for potentially uncomfortable situations.



- Review: Remember to give clear instructions at each visit to ensure success of participants and make it clear of the consequences.

- ☐ Visit 1
- ☐ Visit 2
- ☐ Visit 3
- ☐ Post Visit 3

FM-TIPS Timeline





Clinic Planning and What Not to Do

Clinic Planning



- Screening all new patients with neck and back pain
- Best Practice
- TENS unit charging Plan
- iPad charging Plan
- Hanging the flyers in your clinic

What Not to Do:



- Clinicians need IRB approval prior to beginning the study
- Only trained clinicians can introduce the study or ask questions
 - Example: Front Office person or therapists who are not trained
- Study procedures can start after eConsent is signed by study staff – check clinic email



iPad Information

1



REDCap

REDCap – screening form
iPad password: 932020

2



Quell Flex App

3



Login

Our on-call study
team is
just a few
clicks away

Step 1. Log onto fmtips.org

FM-TIPS.org

Clinician page password: fmtips@hcs2020



Report Folder

FM-TIPS
Fibromyalgia TENS in Physical Therapy Study

Study Contact Information

GENERAL HELP

Telephone: (319) 467-4203
Email: fmtips-studyteam@uiowa.edu

Need Immediate Help?
Monday - Friday
6am to 6 pm
Log into the clinician page on the fmtips.org website. Passcode fmtips.orghcs2020.
Click on the day/time or click on the pdf of the schedule for a study team member phone number.
Website: www.fmtips.org

Quell App ID:
This ID is created by combining:
TIPS (clinic 2-digit number)
(Patient Study 4-digit number)@
quellrelief.com
It will look like: TIPS991234@
quellrelief.com
App password: dailytens

Report Cover

FM-TIPS
Fibromyalgia TENS in Physical Therapy Study

Best Practices

Advertise FM-TIPS

- Place FM-TIPS brochures in the waiting room for patients to see and to ask about the study
- Hang FM-TIPS flyers in the clinic in multiple places: waiting room, restrooms, treatment rooms.
- Send letters about the study to providers in your area.

Best Practices

FM-TIPS iPad Cheat Sheet

FM-TIPS Contact Information

- Telephone: (319) 467-4203
- Email: fmtips-studyteam@uiowa.edu
- Website: www.fmtips.org

iPad Equipment

- iPad Number: CPH-UIOWA-30
- iPad Passcode: 932020
- Cable: Lightning to USB (connects the iPad to charging adaptor)
- AC Charging Adaptor (plugs into wall)

iPad Cheat Sheet

FM-TIPS
Fibromyalgia TENS in Physical Therapy Study

FM-TIPS TENS Unit Receipt

To: *Health System and Clinic Location*
Clinic Contact: *(Clinic Contact Name)*
Date of Receipt *(Date)*

☐ TENS Units

Case #	TENS Unit Number Upper	Check if present	TENS Unit Number Lower	Check if present

TENS Receipt Form

FM-TIPS
Fibromyalgia TENS in Physical Therapy Study

FM-TIPS TENS UNIT ACCOUNTABILITY LOG*

To: *Health System and Clinic Location*
Clinic Contact: *(Clinic Contact Name)*
Telephone: *(Telephone)*

Date Received	Case #	Date Dispensed*	Dispensed To (Subject Initials/ID#)	Quell Login ID **	Tracking Number	Date Returned to University of Iowa

TENS Accountability Log



FM-TIPS

Fibromyalgia TENS In
Physical Therapy Study

THE UNIVERSITY
OF IOWA

VANDERBILT UNIVERSITY
MEDICAL CENTER

FM-TIPS Contact and Study Information



Email: FMTips-StudyTeam@uiowa.edu

Phone: 319-467-4203

iPad password: **932020**

Website: www.fmtips.org

Steps to log into clinician page on back of card

Clinician page password: ***fmtips@hcs2020***

FM-TIPS Study Team Representatives

APTSM:

Barb Van Gorp

barbara-vangorp@uiowa.edu

Genesis PT:

Dana Dailey

dana-dailey@uiowa.edu

RVPT:

Carol Vance

carol-vance@uiowa.edu

BST:

Dana Dailey

dana-dailey@uiowa.edu

Kepros PT:

Liz Johnson

elizabeth.m.johnson@vumc.org

UIC PT:

Andrew Post

andrew-post@uiowa.edu

BST:

Carol Vance

carol-vance@uiowa.edu

RVPT:

Dana Dailey

dana-dailey@uiowa.edu



CLINICIAN LOGIN AND IMMEDIATE HELP CONTACTS

Clinician Login Page: www.fmtips.org



Login

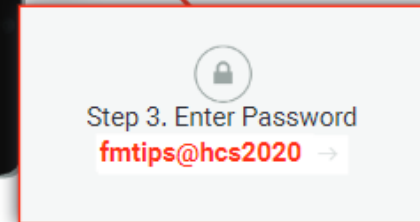
Our on-call study team is just a few clicks away

Step 1. Log onto fmtips.org



LOG IN

Step 2. Click on the "Log in" button



Step 3. Enter Password
fmtips@hcs2020 →



DOWNLOAD PDF
VERSION

Step 4. Download PDF

the study team to let them know
from the study team before

OR

Friday 6am - 8am

Friday 8am - 3pm

Friday 3pm - 6pm

If using a cell phone click on hyperlink with corresponding day/time for automatic call

Continuing Education

Recordings Available

- Dr. Sluka - TENS
- Dr. Crofford - FM
- Dr. Crofford – Pharmacology and FM
- Dr Archer – Psychologically Informed PT
- Movement Evoked Pain Dr. Chimenti and Dr. Post
- Dr. Sluka - Exercise as Analgesia



Upcoming

May – Dr. Martin, Implicit Bias

Provider Follow Up Letter & Brochure



FM-TIPS

Fibromyalgia TENS in
Physical Therapy Study
www.fmtips.org

University of Iowa
Department of Physical Therapy & Rehabilitation Science

Roy J. and Lucille A.
Carver College of Medicine
1-252 Medical Education Building
500 Newton Road, Iowa City, IA 52242-1190
319-335-9791 Tel 319-335-9707 Fax

[Date]

[Provider Name and Credentials],

[Provider Address]

Re: Referrals for the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

We are excited to be a part of FM-TIPS, a NIH funded study, with the University of Iowa and Vanderbilt University Medical Center. This study is recruiting patients through December, 2023.

What is the study about?

We are looking at the use of TENS for pain and function with individuals who have fibromyalgia and chronic spine pain.

Who can participate?

Adults who are 18 years or older who have fibromyalgia and neck or back pain

What do patients do in the study?

- Physical therapy as usual
- Receive and wear 2 TENS units up to 2 hours a day
- Complete surveys at home (5 times over 6 months) and receive payment

If you have patients with fibromyalgia that might benefit from the study, please consider referring to [Clinic Name] for physical therapy. Please reach out to the clinics or the study team with questions. We appreciate your support for this important study.

Kathleen A. Sluka

Kathleen A. Sluka, PT, PhD
Co-Primary Investigator
University of Iowa
FM-TIPS

Leslie J. Crofford

Leslie J. Crofford, MD
Co-Primary Investigator
Vanderbilt University Medical Center
FM-TIPS



Front

Do you have neck or back pain?

Do you have fibromyalgia?

Interested? Ask your Physical Therapist about getting involved

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

Back

Who Can Participate?

Adults who are 18 years or older who have fibromyalgia and neck or back pain

What Will I Do in the Study?

- Receive and wear 2 TENS units
- Physical therapy
- Complete surveys at home (5 times over 6 months)
- Receive payment



How Long Will I Be in the Study?

About 6 months

What is the Study About?

We want to know if use of TENS reduces pain and improves mobility for individuals with fibromyalgia and chronic spine pain





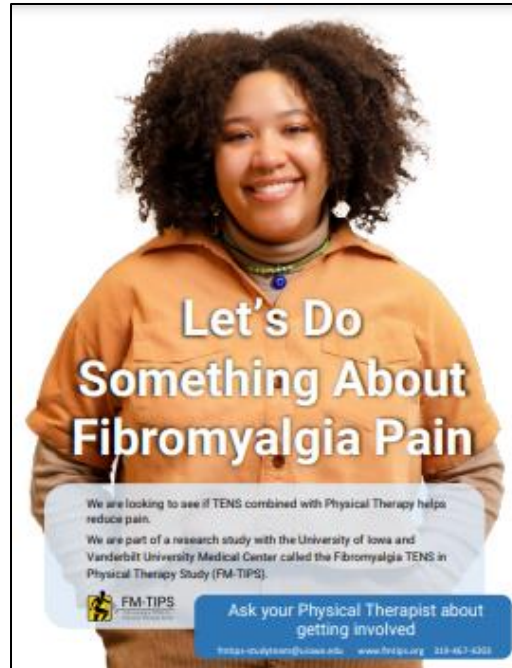
Let's Do Something About Fibromyalgia Pain

ASK YOUR PHYSICAL THERAPIST ABOUT GETTING INVOLVED

We are looking to see if TENS combined with Physical Therapy helps reduce pain.

We are part of a research study with the University of Iowa and Vanderbilt University Medical Center called the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

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



Let's Do Something About Fibromyalgia Pain

We are looking to see if TENS combined with Physical Therapy helps reduce pain.

We are part of a research study with the University of Iowa and Vanderbilt University Medical Center called the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

 **Ask your Physical Therapist about getting involved**

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

Let's Do Something About Fibromyalgia Pain



We are looking to see if TENS combined with Physical Therapy helps reduce pain.

We are part of a research study with the University of Iowa and Vanderbilt University Medical Center called the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

Ask your Physical Therapist about getting involved

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

Let's Do Something About Fibromyalgia Pain



ASK YOUR PHYSICAL THERAPIST ABOUT GETTING INVOLVED

We are looking to see if TENS combined with Physical Therapy helps reduce pain.

We are part of a research study with the University of Iowa and Vanderbilt University Medical Center called the Fibromyalgia TENS in Physical Therapy Study (FM-TIPS).

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

Clinic Flyers

Public Flyer

Can be used at community spaces, provider offices, etc.

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





Questions, Discussion, Next Steps?



- Questions?



- Discussion?



- Next Steps

- IRB Approval Notification
- Ready, Set, Go!



FM-TIPS

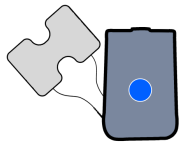
*Fibromyalgia TENS In
Physical Therapy Study*

Contact information:

Telephone: (319) 467-4203

Email: fmtips-studyteam@uiowa.edu

Website: www.fmtips.org



TENS Evidence List



Dailey DL, Vance CGT, Rakel BA, Zimmerman MB, Embree J, Merriwether EN, Geasland KM, Chimenti R, Williams JM, Golchha M, Crofford LJ, Sluka KA. Transcutaneous Electrical Nerve Stimulation Reduces Movement-Evoked Pain and Fatigue: A Randomized, Controlled Trial. *Arthritis Rheumatol*. 2020 May;72(5):824-836. doi: 10.1002/art.41170. Epub 2020 Mar 18. PMID: 31738014; PMCID: PMC7188591.

Dailey DL, Rakel BA, Vance CGT, Liebano RE, Amrit AS, Bush HM, Lee KS, Lee JE, Sluka KA. Transcutaneous electrical nerve stimulation reduces pain, fatigue and hyperalgesia while restoring central inhibition in primary fibromyalgia. *Pain*. 2013 Nov;154(11):2554-2562. doi: 10.1016/j.pain.2013.07.043. Epub 2013 Jul 27. PMID: 23900134; PMCID: PMC3972497.

Johnson MI. Resolving Long-Standing Uncertainty about the Clinical Efficacy of Transcutaneous Electrical Nerve Stimulation (TENS) to Relieve Pain: A Comprehensive Review of Factors Influencing Outcome. *Medicina (Kaunas)*. 2021 Apr 14;57(4):378. doi: 10.3390/medicina57040378. PMID: 33919821; PMCID: PMC8070828.

Moran F, Leonard T, Hawthorne S, Hughes CM, McCrum-Gardner E, Johnson MI, Rakel BA, Sluka KA, Walsh DM. Hypoalgesia in response to transcutaneous electrical nerve stimulation (TENS) depends on stimulation intensity. *J Pain*. 2011 Aug;12(8):929-35. doi: 10.1016/j.jpain.2011.02.352. Epub 2011 Apr 9. PMID: 21481649.

Paley CA, Wittkopf PG, Jones G, Johnson MI. Does TENS Reduce the Intensity of Acute and Chronic Pain? A Comprehensive Appraisal of the Characteristics and Outcomes of 169 Reviews and 49 Meta-Analyses. *Medicina (Kaunas)*. 2021 Oct 4;57(10):1060. doi: 10.3390/medicina57101060. PMID: 34684097; PMCID: PMC8539683

Vance CGT, Zimmerman MB, Dailey DL, Rakel BA, Geasland KM, Chimenti RL, Williams JM, Golchha M, Crofford LJ, Sluka KA. Reduction in movement-evoked pain and fatigue during initial 30-minute transcutaneous electrical nerve stimulation treatment predicts transcutaneous electrical nerve stimulation responders in women with fibromyalgia. *Pain*. 2021 May 1;162(5):1545-1555. doi: 10.1097/j.pain.0000000000002144. PMID: 33230010; PMCID: PMC8049882.

Vance CG, Chimenti RL, Dailey DL, Hadlandsmayth K, Zimmerman MB, Geasland KM, Williams JM, Merriwether EN, Alemo Munters L, Rakel BA, Crofford LJ, Sluka KA. Development of a method to maximize the transcutaneous electrical nerve stimulation intensity in women with fibromyalgia. *J Pain Res*. 2018 Oct 10;11:2269-2278. doi: 10.2147/JPR.S168297. PMID: 30349353; PMCID: PMC6188186.

Vance CG, Dailey DL, Rakel BA, Sluka KA. Using TENS for pain control: the state of the evidence. *Pain Manag*. 2014 May;4(3):197-209. doi: 10.2217/pmt.14.13. PMID: 24953072; PMCID: PMC4186747.

Vance CG, Chimenti RL, Dailey DL, Hadlandsmayth K, Zimmerman MB, Geasland KM, Williams JM, Merriwether EN, Alemo Munters L, Rakel BA, Crofford LJ, Sluka KA. Development of a method to maximize the transcutaneous electrical nerve stimulation intensity in women with fibromyalgia. *J Pain Res*. 2018 Oct 10;11:2269-2278. doi: 10.2147/JPR.S168297. PMID: 30349353; PMCID: PMC6188186.

Sluka KA, Bjordal JM, Marchand S, Rakel BA. What makes transcutaneous electrical nerve stimulation work? Making sense of the mixed results in the clinical literature. *Phys Ther*. 2013 Oct;93(10):1397-402. doi: 10.2522/ptj.20120281. Epub 2013 May 2. PMID: 23641031; PMCID: PMC3788712.



FM-TIPS

*Fibromyalgia TENS In
Physical Therapy Study*

National Institutes of Health Funded Pragmatic Clinical Trial



TENS

Clinician Manual

V2.0 11/22/21

University of Iowa
Vanderbilt University Medical Center



National Institute of
Arthritis and Musculoskeletal
and Skin Diseases

fmtips-studyteam@uiowa.edu

www.fmtips.org

Table of Contents

Welcome to FM-TIPS Study!	3
Research Study Team	4
Contact the FM-TIPS Research Study Team	5
Clinician Feedback	5
Information about the Study	6
Study Overview	6
Study Design.....	6
Study Participants - TENS	7
PT Visit Research Events	8
PT Visit Overview	8
PT Visit 1 Pre-Enrollment Eligibility.....	8
PT Visit 2 eConsent and Enrollment Check	8
PT Visit 3 Research Homework Check	9
Participant Logging on to REDCap for Research Homework	9
PT Visits 1, 2, 3 Table.....	10
TENS: Clinician Scripts for PT Visits.....	12
PT Visit 1: Study Events - TENS.....	12
PT Visit 1: Script Highlights – TENS	13
PT Visit 2: Study Events -TENS	14
PT Visit 2: Script Highlights - TENS.....	14
TENS Instructions.....	15
Quell Flex Application (App) – Download and Pairing	15
Quell Flex TENS Units	15
Quell Flex Quick Start Guide	17
PT Visit 3: Study Events -TENS	19
PT Visit 3: Script Highlights – TENS	19
Completion of the Study	21
Frequently Asked Questions (FAQ).....	21
Appendix:	23
Outline of Study Initiation.....	24
PT Visits 1-3 Decision Tree - TENS	25
Patient Specific Functional Scale – PT Script	26
Sit and Stand Test	28
TENS Home Use Review	29

Welcome to FM-TIPS Study!

Thank you for being a part of the Fibromyalgia Transcutaneous Electrical Nerve Stimulation (TENS) in Physical Therapy Study (FM-TIPS). This is a pragmatic clinical trial sponsored by the National Institutes of Health (NIH) conducted by the University of Iowa and Vanderbilt University Medical Center. A pragmatic clinical trial, sometimes called a practical clinical trial, is a clinical trial that focuses on real-world healthcare situations. The study is conducted in the participant's normal healthcare setting instead of a university's research center.

The goal of FM-TIPS is to determine if the addition of TENS to physical therapy for participants with fibromyalgia helps to reduce pain, increase adherence to physical therapy, reach personal functional goals, and decrease drug use.

This manual contains what you will need to participate in this study:

- Summary of the research study
- How to contact the research study team
- Research Events for Clinicians
- TENS Instruction
- Scripts for Study Events
- Frequently asked questions
- Completing the study

Thank you again for participating in the study. Please let us know if you have any questions.

Thank you,



Kathleen A. Sluka, PT, PhD
Co-Primary Investigator
University of Iowa



Leslie J. Crofford, MD
Co-Primary Investigator
Vanderbilt University Medical Center

Research Study Team

Study Team Lead Investigators



Kathleen A. Sluka, PT, PhD, FAPTA

Professor

Department of Physical Therapy and Rehabilitation Science

University of Iowa

Iowa City, IA



Leslie, J. Crofford, MD

Professor and Chair

Division of Rheumatology & Immunology

Vanderbilt Medical Center

Nashville, TN

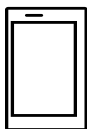
Study Team



Our team includes a group of investigators with diverse expertise including physical therapists, a rheumatologist, clinical trial specialists, and informational technologists.

Additional team members: Dana Dailey, Carol Vance, Dixie Ecklund, Carla Frank, Emine Bayman, Bridget Zimmerman, Michele Costigan, Maxine Koepp, Trevis Huff, George Nye, Rick Peters, Sandra Mostaert, Ruth Chimenti, Andrew Post, Maggie Spencer, Tina Neill-Hudson, Jon Yankey, Elizabeth Johnson, Barb Van Gorp, Adam Janowski, Zack Lemka, Kristin Archer

Contact the FM-TIPS Research Study Team



Quell Flex App: Search “Quell Flex” by NeuroMetrix



Email: fmtips-studyteam@uiowa.edu



Website: www.fmtips.org



Telephone: (319) 467-4203



FM-TIPS Mailing Address:

Neurobiology of Pain Lab
Department of PTRS
University of Iowa
1-248 MEB, 500 Newton Rd
Iowa City, IA 52242

Clinician Feedback

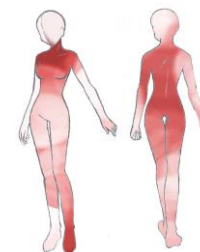
If there is a question or a problem, please get in touch with the research study team by calling (319) 467-4203 or sending an email to fmtips-studyteam@uiowa.edu.

Your honest concerns, questions and opinions are very much welcomed and also allow us to do anything we can to help. Make sure to give us a chance to address any issue you may have.

Information about the Study

Study Overview

- Funded by the National Institutes of Health (NIH), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS); Pragmatic (real-world) clinical trial
- TENS is a safe and effective treatment for movement-evoked pain in FM participants
- Movement pain interferes with physical therapy exercises and activity participation
- TENS is underutilized by physical therapists and other health professionals
- Our recent NIH-funded randomized controlled clinical trial investigating participants with FM showed that active-TENS significantly reduced movement-evoked pain and fatigue after 1 month in-home use when compared to placebo-TENS and no-TENS (Dailey, et al. 2019; <https://onlinelibrary.wiley.com/doi/full/10.1002/art.41170>)
- The current NIH-funded pragmatic trial will test the following **goals**:
 1. Demonstrate the feasibility of adding TENS to usual physical therapy treatment of participants with FM in a real-world PT practice setting
 2. Determine if the addition of TENS to standard PT for FM reduces pain, increases adherence to PT and allows participants with FM to reach their specific functional goals with less drug use

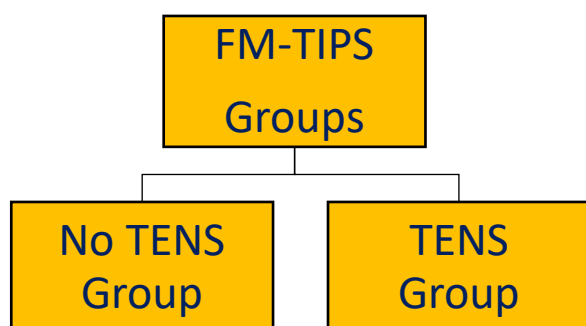


Study Design

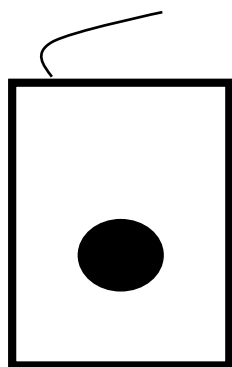
- More than 30 clinics in the Midwest
- Each clinic will enroll 25 participants with FM (therapist will not confirm diagnosis) over the course of the 2 year study.
- Participants referred to physical therapy for fibromyalgia pain or for neck or back pain with FM as a secondary or co-morbid condition.
- Clinics will provide standard physical therapy care and clinics will be randomized to one of two groups:
 1. No TENS Group: Participants in this group will receive TENS units after the first two months of the study to use at home up to four months.
 2. TENS Group: Participants in this group will receive 2 TENS units to use during their PT appointments and at home up to six months.
- Therapists will help with recruitment, reporting of Participant Specific Functional Scale, instruction of study activities, instruction of TENS use for the clinics participating in the TENS Group, and standard PT with or without the TENS unit.
- Participant-led study activities will be done at home at the start of the study and continue monthly for a total of 6 months.

- At 2 months participants in the No TENS group will be given a 2 TENS unit to use at home for the remainder of the study. If the participant is in PT after beginning TENS after 60 days, they should bring to PT sessions to use when active.

Study Participants - TENS



For FM-TIPS, we have two groups of participants, the No TENS group, and the TENS group. Both groups are very important to our study.



Our goal is to have TENS participants wear the TENS units on their upper back and lower back for 2 hours per day, with a minimum of 30 minutes at a time. This means wearing the unit from 30 minutes to 2 hours.

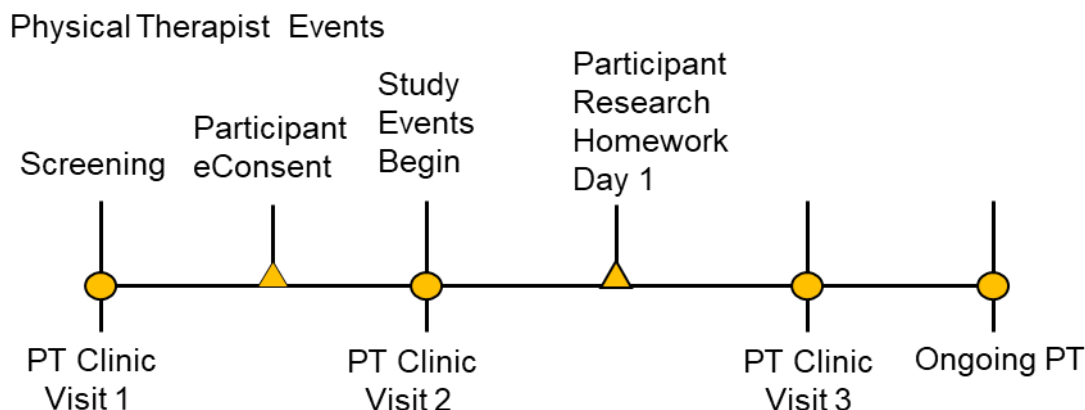
They may wear the TENS units for more than 2 hours a day. This should include wearing the units during the active portions of their physical therapy visits. They have flexibility in how they meet the 2 hours per day guideline. They can divide the time up or do it all at once. If they are unable to wear the TENS unit for the full 2 hours or occasionally miss wearing the unit, we understand.

Participants should open the Quell Flex App **at least once a week** to make sure both units are paired within the Quell Flex App to record their TENS use.

PT Visit Research Events

PT Visit Overview

The research study events for physical therapists include identifying possible participants on the initial PT Visit and facilitating eligibility pre-screening on a tablet (Visit 1), confirming eConsent (PT Visit 2), and confirming completion of the participant research homework session (PT Visit 3).



Physical therapists will be responsible for initiating and monitoring research study events for PT Visits 1, 2 and 3. REDCap is an online data storage system that will collect information from all clinic sites in the study through a tablet or computer into a central database. Participants and clinicians will not have access to other participants' information. Data will be collected and accessed by the University of Iowa for analysis at the completion of the study

PT Visit 1 Pre-Enrollment Eligibility



During the initial PT Visit (Visit 1), participants who are who are eligible to participate and are interested in being a part of the study, will complete an eligibility pre-screen in REDCap on a tablet in the clinic. Following the pre-screening, they receive an email letting them know if they are eligible or not eligible to be in the study.

PT Visit 2 eConsent and Enrollment Check



In REDCap, eligible participants are given the opportunity to read and review the electronic Informed Consent (eConsent). They are instructed to contact research study staff with questions or concerns about the document or study procedures. After questions and concerns have been addressed, the participant will complete the eConsent form in REDCap.

Once the eConsent is completed, your clinic contact will receive an email confirmation that the eConsent was completed. The confirmation of eConsent needs to happen before starting research study events for PT Clinic Visit 2. If the participant has not completed the eConsent, you may take time in the clinic to complete this before your begin research study events for Visit 2.

If you have any concerns that a participant has either not completed the eConsent or may not fully understand the study, please DO NOT perform any study procedures until you confirm the eConsent is appropriately completed with the research study team at the University of Iowa.

PT Visit 3 Research Homework Check



When participant returns on PT Visit 3, you will need to confirm that participant has completed the initial research homework before proceeding. If they have not completed these assessments, they will be required to return the TENS units and be removed from the study.

Participant Logging on to REDCap for Research Homework

Our data collection website is REDCap.



For the pre-enrollment eligibility checklist, your clinic will receive 2 tablets that will have a link to the form the participants will complete. The tablet can also access the eConsent document if the participant did not complete it at home. This is just an example of a REDCap link and does not work:

<https://redcap.icts.uiowa.edu/redcap/surveys/?s=XX32XXLMGHM>

Following eConsent, participants will receive a link to complete the research homework. Each time they click on the link, they will be able to complete their homework on REDCap – This the order of research homework:



- Rate pain and fatigue at rest
- Complete sit and stand test, rate pain and fatigue during the test
- Begin a 30 minute TENS session
- Answer survey questions
- After 30 minutes, rate pain and fatigue
- Complete the sit and stand test, rate pain and fatigue during the test
- End 30 minute TENS session or may continue with TENS

PT Visits 1, 2, 3 Table

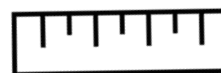
PT Visit	Physical Therapist Responsibility	Information to Know for this table (Words in blue are study continuation points) (Words in orange are study decision points) (Words in red are study stopping points)	Equipment or Materials Needed
PT Visit 1	Identify possible participant	Diagnoses: Fibromyalgia Neck pain and fibromyalgia Back pain and fibromyalgia	Recruitment Brochure
		Inclusion Criteria • Age 18 or above • Clinician diagnosis of fibromyalgia (reported by participant) • Referred for land-based PT for treatment of FM or neck pain or back pain with FM as secondary diagnosis in past medical history • Able to provide informed consent • Fluent in reading English • Willing to use TENS	
		Exclusion Criteria 1. Contraindications to TENS use (See Appendix 1 for Precautions and Contraindication references): a. Pacemaker, defibrillator, implanted neurostimulator or implanted device b. Epilepsy c. Currently pregnant or plan to become pregnant in the next 6 months d. Allergic reaction to patches with gel e. Current treatment for cancer 2. Currently enrolled in another pain control study 3. Use of TENS within the last 30 days 4. Clinically unstable medical or psychiatric issues	
	PSFS	Patient Specific Functional Scale Measure completed during PT evaluation	Complete in electronic health record
	Participant Interested or not	REDCap pre-screening on tablet in clinic If eligible, participant continues to eConsent. Participant must complete eConsent before visit 2 begins If not interested, declines.	Tablet

PT Visit 2	Confirm eConsent completion	Check email to confirm eConsent completed If completed; continue If eConsent not complete: - Participant may complete eConsent on the tablet in the clinic prior to starting visit 2 - Participant may decline to participate	Email
	Study Procedures during Visit 2	Importance of Sit and Stand Test Study supplies TENS instruction	Supplies for TENS Group Study bag, Participant Manual, TENS Manual, Quell App Manual, Quell App quick start guide 2 TENS units, wires, electrodes TENS pouch TENS case
PT Visit 3	Confirm Research Homework completion	Check email to confirm research homework completed - If research homework is incomplete, study ends, return of TENS units and electrodes - If research homework is completed, study continues TENS during activity in PT clinic	Email
Ongoing PT	PSFS	PSFS completed if participant is in PT at day 30 and day 60	PSFS

TENS: Clinician Scripts for PT Visits

PT Visit 1: Study Events - TENS

- Identify possible participant
 - Access to the internet
 - Able to provide informed consent
 - Able to read English well
 - Diagnosis of FM
- Patient Specific Functional Scale
 - See PSFS script and form in appendix
- Provide study information
- Possible participant to complete pre-enrollment screening on tablet



To Identify Possible Participant

- Screen all new patients with diagnosis of chronic neck or chronic back pain
 - The screen on the table takes less than 5 minutes
 - The screening on the tablet will ask about diagnosis of fibromyalgia by a clinician

PT Visit 1: Script Highlights – TENS

Provide study information to participants

- We are conducting a study in partnership with the University of Iowa and Vanderbilt Medical Center to test a non-drug treatment for FM participants.
- We are testing the effect of combining TENS treatment with physical therapy for pain relief for individuals with fibromyalgia.
- The study team has done research showing that TENS helps to relieve fibromyalgia pain during activities like exercise or household chores.
- Now they want to see if using a TENS unit will make physical therapy easier and more productive.
- Compensation is included. And all the materials you will need are provided by the study team.
- Give participant flyer and point out contact information and other relevant points.
- Does this sound like something you're interested in?
 - If no: stop
 - If yes: continue

Pre-Enrollment Screening

- “The next step is to have you answer screening questions on a tablet to determine if you meet the criteria to participate.”
- Direct the participant to area where you want them to complete the tablet screening
- “When you're done, return the tablet to the front desk staff.”

eConsent

- If the participant is ready, participant can review the eConsent document and sign.
- If the eConsent is not signed at PT visit one the study team will contact the participant by email with materials to review and a document to sign. This will provide consent to participate in the research.
- Participant should contact the study team with questions and PT can answer questions at the next appointment.
- **Completion of eConsent is a requirement for participating in the study.**

PT Visit 2: Study Events -TENS

Study Events

- Verify eligibility and eConsent - check email
- Sit and Stand Test Importance
- Quell Flex App
- TENS unit instruction
- Continue with PT if time allows

PT Visit 2: Script Highlights - TENS

Eligibility and eConsent Verification

Eligibility

Visit 1- Fails screening

- Question: why don't I qualify?
- I am sorry you are not able to be in the study
- "The computer program scores the questions so I cannot really say. The study team sets criteria for participation.

eConsent

- If eConsent document has not been signed by the participant, the **participant MUST complete the eConsent** before continuing, electronically on tablet or participant's phone using link sent to participant by email.

Sit and Stand Test Importance

- I want to emphasize the importance of doing this "homework". It **must** be done before you come back for your next visit, (Give date if known) for you to continue in the study.
- There are several times when we ask you to rate your pain and fatigue on a 0-10 scale. These ratings are **very important** to our study team. You will do these ratings at rest and immediately after doing a test where you get up and down from a chair 5 times in a row.
- We are studying the effectiveness of TENS on rest and on movement pain, so these assessments are important now at the beginning, and all the way through the end of the study.

TENS Instructions

See **TENS Manual** for more detailed instructions, Contraindications and Precautions

Quell Flex Application (App) – Download and Pairing

Download the Quell Flex App on participants smartphone

Serial number entered by participant into app (**circle with two numbers**)



- Help participant **pair** the TENS units
- Instruct the participant to open the app **once per week** so the usage data can be downloaded to the study personnel.

While app is downloading: let's look at all your study materials

Manuals and Guide

- TENS Participant
- Quell Flex TENS Manual
- Quell Flex App Manual
- Quell Flex Quick Start Guide

TENS Equipment

- 2 TENS units
- 2 color coded wires
- 2 chargers and 2 charge cords
- 1 carrying pouch
- 1 case
- 10 electrodes

Quell Flex TENS Units

- If needed, review description of TENS for participant, see appendix for example
- 2 TENS units: **Upper back – purple** and **Lower back - orange**
- Therapist uses one TENS unit and participant uses the second TENS unit
 - (Participant mirrors therapists demonstration)
- Connect color coded wires to colored units
- Connect wires to electrodes
- Clean skin, apply electrodes to upper and lower back
- Begin TENS treatment and pair both TENS units to the Quell App
- Review TENS intensity increase and decrease with the blue button and Quell Flex app
 - Gradually increase the intensity until the participant feels a strong, comfortable, non-painful sensation.
 - As users get used to the sensation, they are often able to turn the unit up further after a few minutes of wear. It is important to keep this in mind as the participant wears it at home.
 - The unit will max out at an intensity of 100 mA.
- Electrode placement, use and care
- Review stopping a treatment with the blue button and the Quell Flex App



- Review TENS units charging – charging port, time to recharge and charger itself
- Explain lights on the TENS units
 -  ○ Single white flashing light – unit is charged and ready for treatment
 -  ○ Double white flashing light – TENS treatment is active
 -  ○ Blue light – poor connection (electrode, wire out of unit, wire out of - electrode)
 -  ○ No light after pressing the on button – time to charge unit
- Resetting the TENS Unit
 - The Quell Flex TENS units automatically ramp up to the last intensity used. Clinics and participants may want to reset the units to the default of 5mA, the lowest setting.
 - While the TENS unit is off, press and hold the button for 2s (until rapid blinking of the white light is shown).
 - The unit then ramps up to 5mA [over 2 minutes] the first time you run a treatment.
 - Patients are then to increase to “strong but comfortable” for the session.
 - The next time they start a session, the unit ramps up to the last mA they utilized. They should further increase/decrease intensity to “strong but comfortable” for every session.
 - Remember, the number does not matter, the sensation of “as strong as possible while still being comfortable” is important. Intensity is linked to effectiveness!

Dispensing the TENS units

As part of PT Clinic Visit 2, when appropriate, therapists will instruct the participant in the use of TENS. A separate booklet is provided for TENS instruction. After dispensing the unit, please document on the TENS log in your clinic which unit has been dispensed.

TENS use at home



Participants are asked to use the two TENS units to the upper back and lower back for 2 hours a day. We ask that they use the TENS units at a minimum of 30 minutes per session. They are welcome to break up the sessions through the day or do them all at once. Please assist the participant to find what works best for them. They may use the TENS units for more than 2 hours. They should try to wear them when active. ” Do what works for you.”

TENS Use during PT sessions



Participants are asked to bring their TENS units to each physical therapy session. They should use them during activities in the clinic and during activities in the clinic and for a minimum of 30 minutes. This means that they may need to finish the TENS session after the PT session has ended.

Operating the TENS unit



You will be given a separate booklet with instructions for operating the TENS units. If you have a question or a concern, please call or email the research study team.

Quell Flex TENS Application, (App)

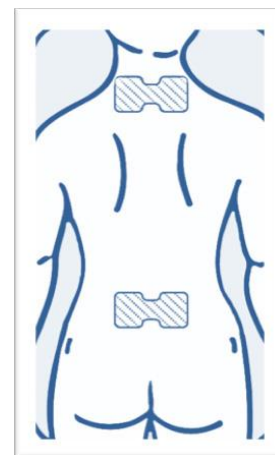


You will be given a separate booklet for the Quell Flex App. Please remind the participant to log into the application **at least once a week** so that their TENS wearing time is recorded.

Quell Flex Quick Start Guide

To begin a treatment:

1. Make sure the TENS units are OFF and fully charged.
2. The charger port is on the side of the unit. A full charge will take 1.5-2 hours.
3. Remove the unit from the wall charger.
4. Attach the lead wires to the electrodes.
5. Apply electrodes to clean dry skin.
6. Attach the color-coded lead wires to the TENS unit.
7. Turn the unit ON by pressing the blue button on the front.
8. The white light on the top of the unit will flash. (two quick flashes)
9. The stimulation will increase to a set level over two minutes.
10. Increase the intensity to be strong but comfortable by holding down the blue button.
11. After a few minutes, it may seem the stimulation has gone down. This is normal as your body gets used to the TENS.
12. You should turn up the intensity to keep it feeling strong, but comfortable.
13. Decrease the intensity by pressing and releasing the blue button.
14. The timer automatically sets for 60 minutes.
15. You may use the unit as much as desired.
16. For the study, we are asking you to wear TENS for 2 hours each day.
17. Wear the unit for a minimum of 30 minutes each session.
18. Try to wear your TENS when active.

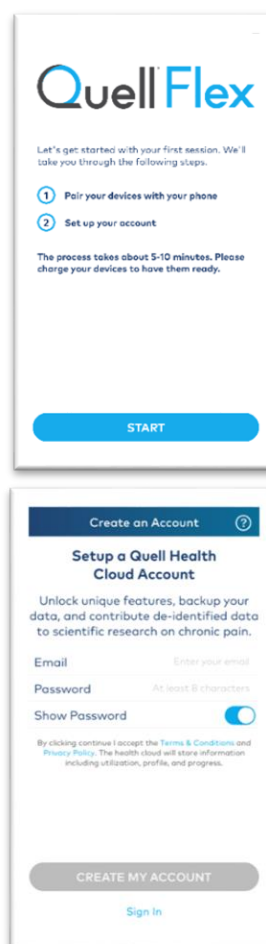


To end a treatment:

1. Press and release the blue button 4 times in a row.
2. You may keep the electrodes in place for your next treatment.
3. Secure the units and wires in the pouch or a pocket.
4. If you see a flashing yellow light, it means there is a problem with connectivity. Turn the unit OFF. Check to make sure the wires are inserted into the unit as well as into the electrodes. Also, check to make sure your electrodes have good contact with your skin.
5. When you are finished with treatments for the day, remove your electrodes.
6. Find the white non-sticky section in the middle.
7. Gently pull to release the electrode. Hold your skin down next to the electrode as it releases.
8. Return the electrode to the plastic sheet and place in the zip lock bag.

Using the Quell Flex Application (App):

1. Using your mobile device or tablet, open the App Store or Google Play
2. Search “Quell Flex” by NeuroMetrix and download the app to your device.
3. Make sure Bluetooth is turned on and that your device is running iOS 10 or later, or Android 6 or later.
4. Launch the Quell Flex App and follow the step-by-step instruction within the app to pair both Quell TENS units.
5. Instructions within the app will guide you through two steps:
 - Set up your Health Cloud Account
 - Pair your devices with the phone
6. Creating a Health Cloud Account
 - For the email address, enter your unique study ID that you will receive from the research study team (for example XXXX from site YY) to TIPSYYXXXX@quellrelief.com
 - Password: **dailytens**
7. You will pair both the “Upper” and “Lower” Quell TENS units. Once you enter the last two digits, the device will recognize your Quell Unit as either “Upper” or “Lower.”
8. **In order to capture your TENS use, we need you to open the app and make sure both units are paired within the Quell Flex App at least once a week.**



For complete FM-TIPS Quell Flex instructions please refer to your Quell Flex TENS Manual and Quell Flex App Manual!

PT Visit 3: Study Events -TENS

Study Events

- Verify Research Homework Completed
 - If participant does not complete Research Homework, gather TENS units
- Apply TENS during activity in PT
- Complete PT treatment
- Scenarios that may occur Visit 3
 - Participant did not bring TENS units or TENS units not charged-use clinic units
 - Change of heart about continuing in the study – gather TENS units

PT Visit 3: Script Highlights – TENS

Scenario	Therapist Script Ideas
No research homework completed	I see that you did not complete the research homework for the TENS study. For participation in the study, the surveys and testing done at home must be completed. I am sorry, but because we are missing that data point, we will have to end your participation. We will proceed with your physical therapy visits and if you're interested in TENS, I can include use of a different TENS unit as a part of the treatment. I can take your bag and get things returned.
TENS Units	
Participant forgot to bring TENS units and supplies or Participant brought TENS units and supplies but no charge	OK _____ For today I can use emergency backup TENS units and electrodes we have here in the clinic. Just a reminder this won't get captured on your TENS app for TENS use. <i>*** at the end of the session***</i> Great work today. I am glad were able to keep you in the study with our emergency backup equipment. For the rest of the visits, please remember to bring your supplies [TENS units, wires, electrodes] as this will help keep a more accurate record of your TENS usage. Make sure your units have a good charge before you arrive. Is there a good way you can think to help remind yourself to bring the study equipment [TENS units, wires, electrodes] /have the units charged each time?

Participant suggests keeping TENS units and supplies in the car	That's not a great plan as you should be wearing the units during the day. That's not a great plan because the units should not be kept in hot or cold temperatures What about this idea? Note on calendar, Phone reminder, note on fridge, note in the car
Change of Heart	
I don't want to do this TENS thing	OK. Can you tell me a little detail about this decision? It is important for us to be able to make our study better. Possible reasons • <i>Money</i> • <i>Time to put it all on</i> • <i>Did not help my pain</i> • <i>Hate the set up/can't get to my back</i> • <i>No helper to get it set up</i> • <i>Smart phone app too much for me</i> • <i>Anxiety with TENS</i> • <i>Itchiness with TENS</i> • <i>Nausea</i> • <i>Skin irritation with TENS</i> • <i>Other</i>
The study is too much work	OK. The home activities can be a bit of work, but from here on out will just be using TENS at clinic visit and at home. You will do the questionnaires and sit and stand test. In light of that, would you like to continue?
I do not like the TENS units at all.	It is always your decision to participate in the study. Before you decide for sure, can you tell me more about why you did not like TENS? Are you willing to have me set it up today and make sure everything is set correctly?
I brought my equipment and supplies to PT Clinic and I do not want to continue (final answer)	Ok. You may keep the bag if you would like. I will take your study equipment and process it for return. Thank you for your feedback. Let's get started with your therapy
I have decided I do not want to participate; but did not bring equipment (or final answer)	OK. Bring it to your next visit or drop it by to the front desk. After we account for the equipment [Two TENS, two wires, electrodes, case, and pouch] we will process your payment for the time you spent on the study. Let's get started on your therapy.

Completion of the Study

The study activities for participants will be completed after 6 months of participation. They will be able to keep the TENS units when the study is complete. They may contact the manufacturer, Quell, for electrode purchase.

Frequently Asked Questions (FAQ)

1. Are participants paid for participating in the study?
Yes, each will be paid a total of \$200 if they complete all study visits. They will also receive 2 free TENS units and electrodes for 6 months. If they do not complete all study visits, they will be paid for the visits they complete on a pro-rated basis.
2. Can a study participant end participation in the study at any time?
Yes, they can contact the research study team by phone or email to end their participation.
3. Will there be any additional cost to study participants for participating in the study?
No, there will be no extra cost to the study participant.
4. What happens if a study participant becomes sick or injured during participation in the study?
The study participant should contact Dr. Dana Dailey or Dr. Kathleen Sluka as soon as possible to determine if it is safe for them to continue in the study.
Dr. Dana Dailey or Dr. Kathleen Sluka 319-467-4203.
5. What happens if a study participant becomes pregnant during participation in the study?
They should stop using the TENS unit immediately and contact Dr. Dana Dailey or Dr. Kathleen Sluka as soon as possible.
Dr. Dana Dailey or Dr. Kathleen Sluka 319-467-4203.
6. Can a study participant take all of their normal medications while using a TENS unit?
Yes, they should continue with medications as usual.

7. Can a study participant continue other treatments while using a TENS unit, i.e. acupuncture?

Yes, and if you have questions, please contact the research study team.

8. Will a study participant's individual information from the study be shared?

No, results from the study will only be shared as aggregate results or as de-identified data if any individual results are shared.

9. What are the risks associated with TENS treatment?

Study participants may experience local skin irritation (caused by the adhesive in the TENS electrode), mild redness at the site of the TENS stimulation, a burning or pricking sensation, discomfort, or aggravation of pain from TENS.

10. Will using a TENS unit restrict activities?

The only activities limited while using a TENS unit are those associated with water, i.e. bathing, showering, swimming, etc.

11. What are the alternative options if a participant chooses not to do this study?

They could receive standard physical therapy without TENS, or you could discuss the use of an alternate TENS unit with them and the therapy could be performed without participation in the study.

12. Will the clinic be paid as part of being in the study?

Yes, for each participant enrolled, your clinic will receive \$200 to cover the cost of participating as a clinician in the study.

13. What if a participant does not want to continue in the study?

The participant can stop participation at any time and will need to contact the study team. Also, they can continue with their usual physical therapy care.

14. When should a participant return their TENS unit?

If a participant has not completed their research homework prior to Visit 3, then the TENS units should be re-collected by the PT.

15. What do I do with any TENS unit that is returned/re-collected from a participant?

If a TENS unit is returned or re-collected, please contact the research study team.

Appendix:

The appendix has forms that we will laminate for you to use in the study along with the scripts from Visit 1, 2 and 3

- Outline of Study Initiation
- V1, V2, V3 Decision Tree
- PSFS Script and Scale
- Sit and stand test
- TENS Home Use Review

Outline of Study Initiation

PT Visit 1: Eligibility and study introduction

Complete Participant Specific Functional Scale during evaluation
Identify possible participants for the study
Give brochure to interested participants
If interested, have participant complete screening on tablet
Participant will need to complete eConsent on REDCap prior to Visit 2

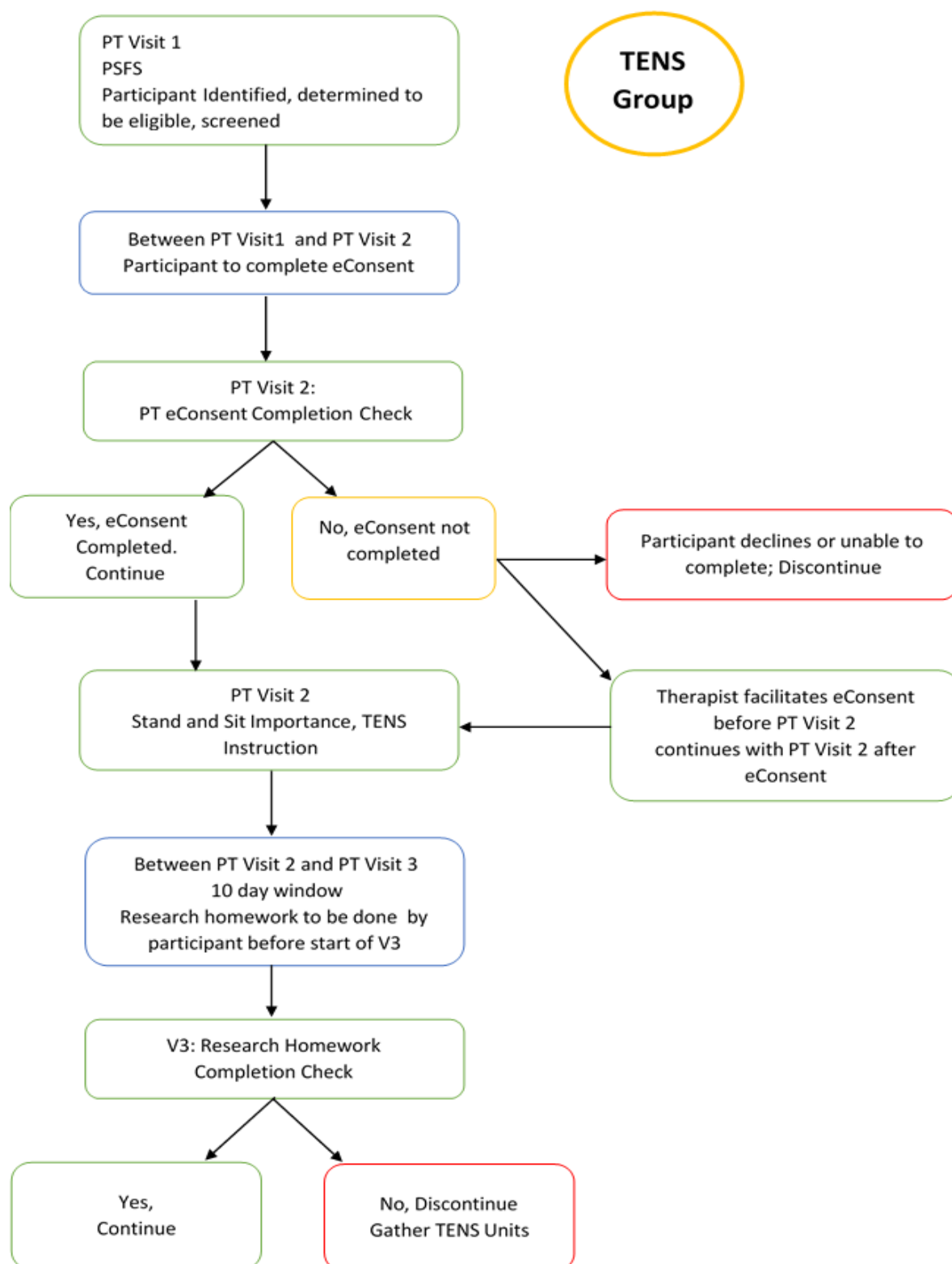
PT Visit 2: eConsent and Instruction

Check on eConsent completion, if not completed offer tablet or participant declines
If eConsent completed, begin study activities
Sit and Stand Test Importance
TENS instruction
Study Supplies given to participant

PT Visit 3: Research Homework Check

Check on completion of research homework
Apply TENS
Complete PT treatment
If participant does not complete research homework, participant returns TENS units to clinic

PT Visits 1-3 Decision Tree - TENS



Patient Specific Functional Scale – PT Script

- PT to complete PSFS at Initial Evaluation and every 30 days while in PT

Clinician:

- We are going to complete an outcome measure called the Patient Specific Functional Scale
- For this measure, I will need you to select 2 activities that are you are having difficulty doing because of the pain or symptoms you are experiencing.
- The selected activities can be any task you complete during a typical day that you notice are impacted by your pain or symptoms.
- *If participant has difficulty reporting specific activities, the clinician can provide examples of activities with participant based on subjective examination and reported functional limitations*

Participant:

- Participant selects at least 2 activities (can select up to 5)

Clinician:

- That is a great set of activities that you selected
- Next, I am going to have you rate how much difficulty you are having completing each specific activity on a scale of 0 to 10. Please note, this scale is an activity scale, and it is opposite of the pain scale
- “0” means that you are unable to complete the activity and “10” means you are having no difficulty performing the activity or at a level prior to your condition.
- *Clinician establishes that the participant understands the scale as this is a reverse scale outcome measure.*

Participant:

- Participant provides rating on 0-10 scale for at least 2 separate activities.
- *Participant reported value is then recorded by PT for each activity*

PSFS Scoring

- Total Score = sum of the activity scores/number of activities
- Minimum detectable change (90%CI) for average score = 2 points
- Minimum detectable change (90%CI) for a single activity score = 3 points

Patient Specific Functional Scale FM TIPS



Sit and Stand Test

The purpose of this test is to examine your pain during an activity.

Your goal is to rate your pain and fatigue **BEFORE** you do your activity and then **DURING** the activity.

Activity: Standing up and sitting down from a chair 5 times

What you need to do the test:

- Standard hard-back kitchen chair without wheels
- [with arms if possible]
- Comfortable walking shoes
- Computer/tablet



How to do the sit and stand test:

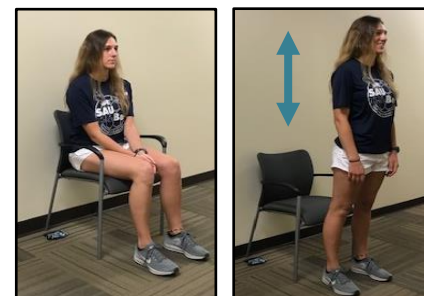
1. Wear comfortable shoes (No sandals/slippers/bare feet).
2. Find a place to put your chair so it won't move [against the wall or against a stable object such as a table].
3. The chair should be in a location in your home where your computer/tablet/smartphone is close so you can enter pain and fatigue ratings.
4. Rate your pain and fatigue **BEFORE** you do the activity and record in REDCap.
5. Stand up and sit down from the chair 5 times.
6. Rate your pain and fatigue after you do the activity. You should rate your pain and fatigue at the highest rating that occurred **DURING** the activity and record it in REDCap.
7. Now you are ready to begin the test!



Step 1: Rate your pain and fatigue and record it in REDCap on your computer or tablet

Step 2: Perform the Activity

1. Sit on the chair. Place your feet shoulder width apart.
2. Rise up to a full standing position and then sit back down just so that your bottom and the back of your thighs make full contact with the chair [no need to have back touch the backrest]. If your chair has arm rests, don't use them unless you need them.
3. Stand up and sit down four more times as quickly and safely as possible (total of 5 times standing and sitting).



Step 3: Rate pain and fatigue and record it in REDCap on the computer or tablet at the highest rating the occurred during the activity.

TENS Home Use Review

See TENS Manual for more details

Research has shown that a minimum of 30 min TENS application is required to receive benefits, so once you turn on the TENS units, please wear it for a minimum of 30 minutes.

For this study we are asking that you wear the TENS for 120 minutes each day during activity. This can be as one continuous session or multiple 30 minute sessions.

You may use the TENS as often as you would like, including exceeding the 120 minutes per day.

Research has also shown that TENS works best for pain during activities and not as well when sitting still or laying down.

For this study you are asked to wear the TENS units **when moving around**. Examples include exercise, walking, household chores or working.

- For the purpose of this study we ask that you **wear the electrodes on your upper back and your lower back**.
- For this study we ask that you wear them in the designated spots so that we collect good data.
- Also, we ask that you **wear both units** at the same time. Refrain from only turning on one unit. If you have a reason preventing you for using them at both locations, please contact the study team.
- The units record information for the study, such as number of sessions, average intensities, total wear time etc. so make sure you are **the only person wearing** them.
- After this study is over, you will keep your units and can use them for other areas of pain. The Quell support team will be able to assist you with the TENS units after the study is over.
- **Electrodes are designed to last 10-14 days**. We ask that you get as many wears out of one electrode as long as it remains sticky and in good condition. It is important to keep the electrodes on the plastic insert, inside of the zipped package when you are not wearing them. This will keep them sticky for a longer period of time.

- If you notice the **corners start becoming un-sticky** you can wet your fingertip, run it over the electrode to get it damp/ slightly wet and let it air dry for 30 seconds. This will allow the electrode to become tacky.
- For a good TENS treatment it's important for you to **keep your skin clean** (even if it's with a wet washcloth before applying the electrodes) and the electrodes sticky for better electrical conduction.
- It can be beneficial to warm up the electrodes by holding them in your hands for a few minutes prior to putting them on.

If you wear the unit for 30 minutes and you want to take a break, you can always shut off the unit but leave the electrodes on and you can roll up the wires and put them in a pocket. This will save you a step or two when hooking up the unit for the next session.

- This will also keep the electrodes sticky for a longer period of time by decreasing the number of times you put them on and take them off.
- **The supply of electrodes is intended to last 2 months.** Cleaning your skin and keeping the electrodes on the plastic and in the bag when not in use is important to keep them in good shape for as long as possible.
- The study team will send you more electrodes after the 60-day (2 month) check-in. If you need some sooner, you can contact the research study team for more.
- Help participant to think about her daily routine and **identify times** when she can/should wear her TENS unit.
 - While doing housework
 - While getting ready in the morning (not in the shower or bath)
 - While taking an evening walk
 - While shopping or running errands
 - While doing PT exercises at home
 - While at work

Remind participant of contact information for the study team and Quell that is found in the TENS unit materials. The participant is encouraged to reach out for help and questions as needed.