

Let's Do Something About Fibromyalgia And Chronic Pain

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

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



You may be eligible if you have
fibromyalgia or chronic pain

HERE'S WHAT THE STUDY INVOLVES

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

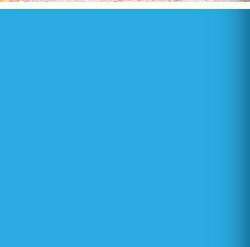
**CONTACT THE RESEARCH TEAM ABOUT
GETTING INVOLVED**

fmtips-studyteam@uiowa.edu www.fmtips.org 319-467-4203
OR CONTACT THE CLINIC DIRECTLY: [clinic phone here]

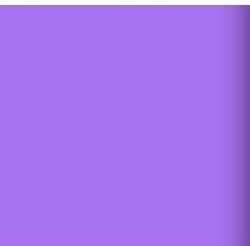




Do you have
chronic pain?



Do you have
fibromyalgia?



Interested? Ask your Physical
Therapist about getting involved

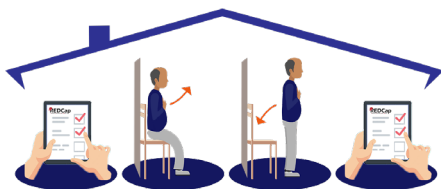
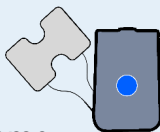
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fmtips-studyteam@uiowa.edu

Who Can Participate?

Adults who are 18 years or older
who have fibromyalgia and chronic
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 pain



FM-TIPS
Fibromyalgia TENS In
Physical Therapy Study

DO YOU HAVE FIBROMYALGIA?

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

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

**Join the Fibromyalgia TENS in Physical Therapy Study
TODAY!**

**SWITCH OUT
CLINIC LOGOS**

[street name] [city, state zip]
[phone number]



VANDERBILT UNIVERSITY
MEDICAL CENTER



FM-TIPS
Fibromyalgia TENS in
Physical Therapy Study

FMTIPS.org
319.467.4203

fmtips-studyteam@uiowa.edu



FM-TIPS

500 Newton Road, 1-252 MEB

University of Iowa

Iowa City, IA 52242-1089

What do I need to do?

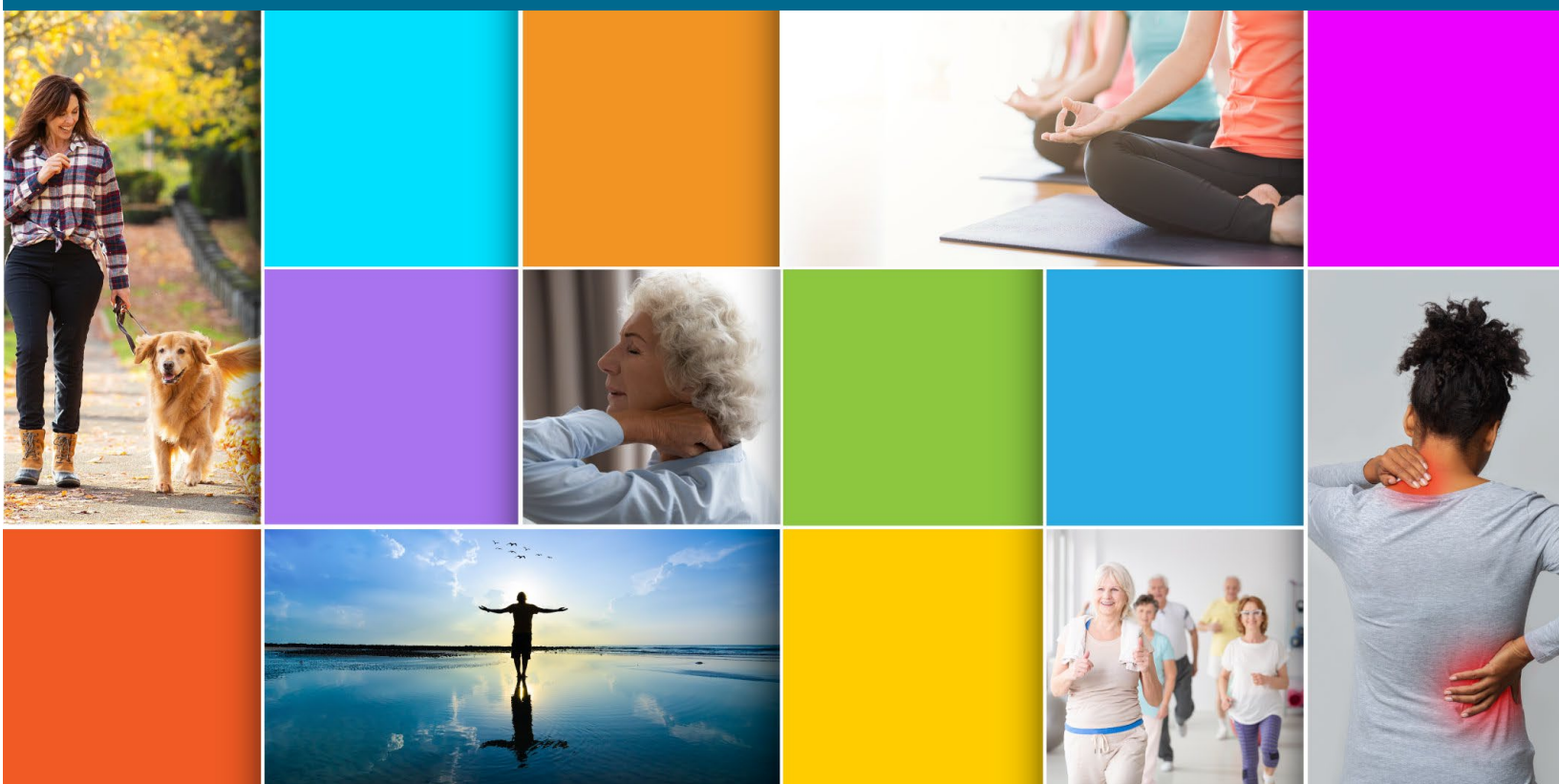
- Visit [Clinic Name]
- Complete online surveys at home
- Wear a TENS unit for 2 hours a day

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

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

Do you have Fibromyalgia?

Are you interested in a research study?

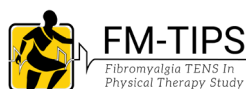


- We are looking to see if TENS combined with Physical Therapy helps reduce pain for people with Fibromyalgia.
- Participation in the study involves visits to a local Physical Therapy Clinic and doing surveys at home. You will be responsible for payment for the physical therapy services.
- You will be 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





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).



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FM-TIPS
Fibromyalgia TENS In
Physical Therapy Study

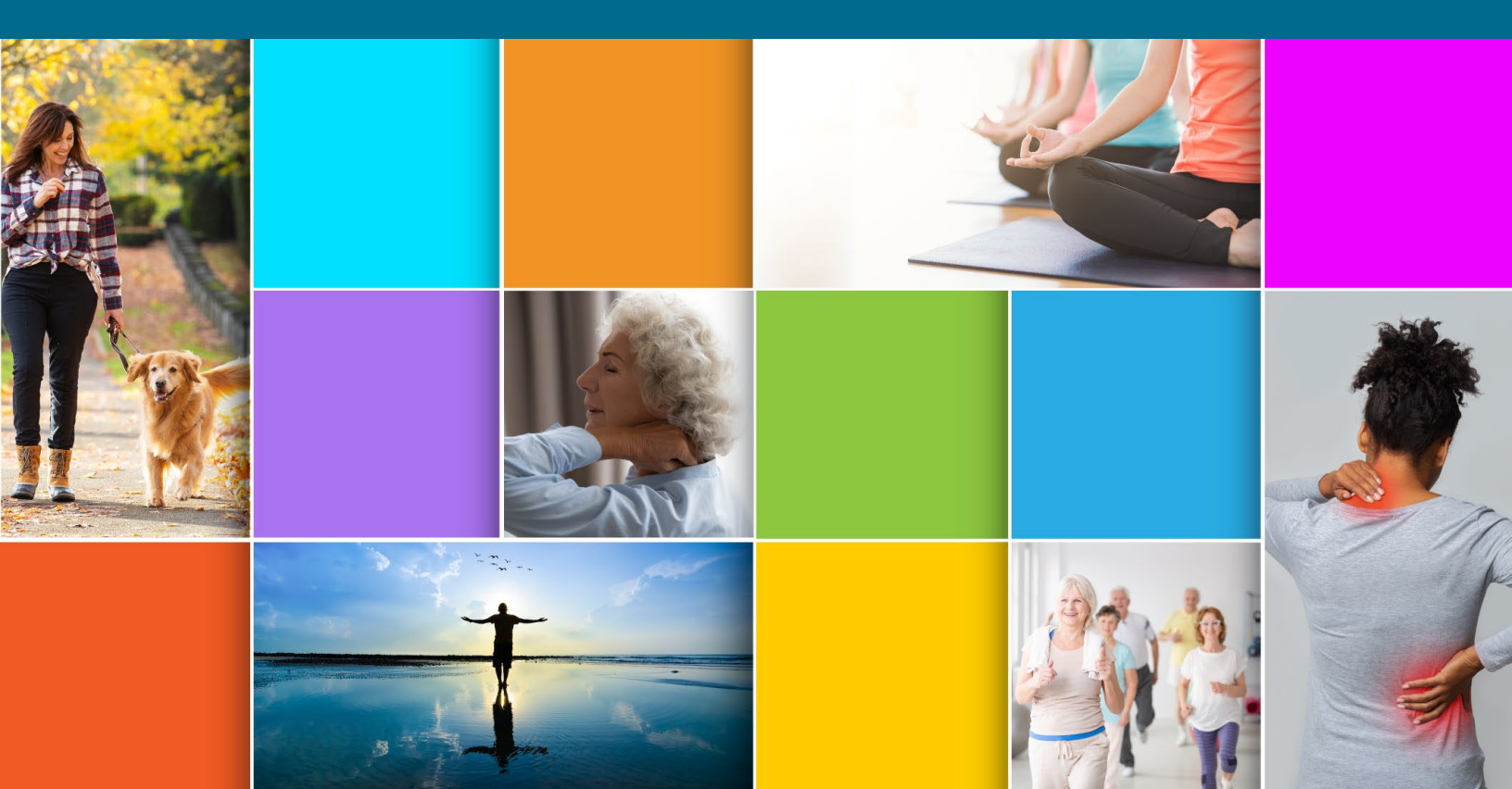
Ask your Physical Therapist about
getting involved

fmtips-studyteam@uiowa.edu

www.fmtips.org

319-467-4203

Let's Do Something About Fibromyalgia Pain



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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



FM-TIPS

*Fibromyalgia TENS In
Physical Therapy Study*

National Institutes of Health Funded Pragmatic Clinical Trial



No TENS

Participant Manual

V3.0 12/16/21

University of Iowa
Vanderbilt University Medical Center

fmtips-studyteam@uiowa.edu



National Institute of
Arthritis and Musculoskeletal
and Skin Diseases

www.fmtips.org

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Welcome to the FM-TIPS Study!

Thank you for participating in 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) between 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 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
- Study Events for Clinicians
- TENS Instruction for your information
- 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

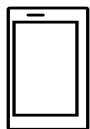
Study Team



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

How to 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

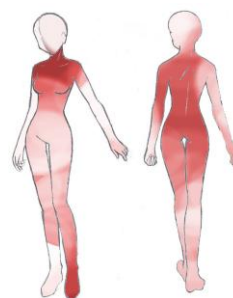


FM-TIPS Mailing Address:
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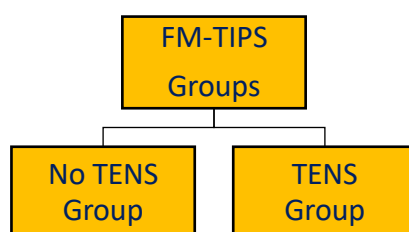
Study Overview

Study Design

- To be included in the FM-TIPS study
 - You must have a diagnosis of fibromyalgia from your physician.
 - You must be coming to physical therapy for fibromyalgia OR neck or back pain with a diagnosis of fibromyalgia.



- There are two patient groups in the FM-TIPS study: No TENS or TENS groups.



Study Participants – No TENS

- You are attending a physical therapy clinic that has been designated a clinic for No TENS. This means that you will receive standard physical therapy without the addition of TENS treatment. After 60 days of participation in the study, you will receive TENS units for the remaining 60 days.
- Your group is a very important group in the study. By having you do the first 60 days in the study without TENS, you provide important data while still receiving standard physical therapy care. We could not do the study without you!
- You will receive 2 TENS units and supplies at home after the first 60 days of the study. You will receive telehealth instructions with a study team member on how to use the TENS units after the 60 day period. You will use the TENS units for four months.
- Your physical therapist will provide standard physical therapy treatment and guide you with instruction of study-related activities along the way.



Requirements of participating in the study:



- You will complete research homework that include answering several questionnaires and doing a sit and stand test. The study activities will take about 45 minutes.
- The study requires doing research homework over 6 months. Schedule of Home Activities Day 1, 30, 60, 65, 90 and 180.
- For no-TENS, you will receive 2 TENS units after 60 days and use them during exercise or when active for next 4 months. If you are attending physical therapy when you begin the TENS portion of the study, you will bring your 2 units to your PT visits.

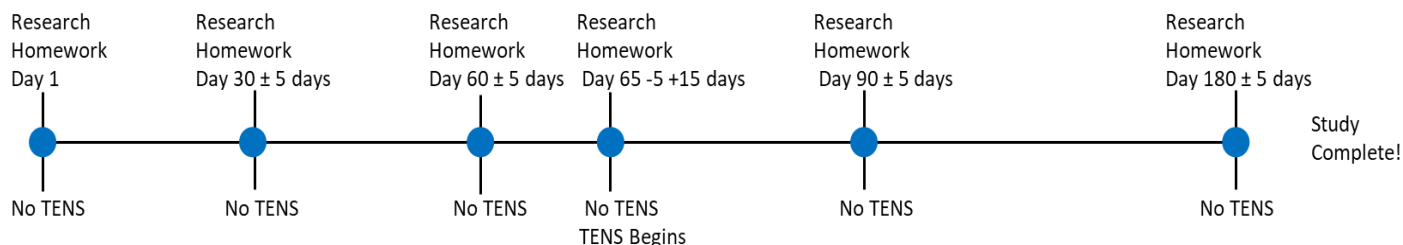


- **Two TENS devices and supplies and up to \$200 will be awarded to you for completing activities during the study.**

Participation in the study is not required to continue with your physical therapy care. However, you will not be enrolled in the study if you decline to participate.

Timing of Research Homework – No TENS

No TENS Participant Research Homework



PT Visits 1-3 Overview - No TENS

Visit 1:

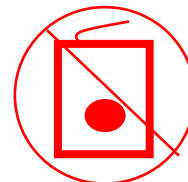
- Complete pre-screening on tablet in clinic.
- Patient Specific Functional Scale with Physical Therapist

Before Visit 2:

- Review and complete informed consent form, called eConsent. This is **required to be enrolled and begin participation** in the study.

Visit 2:

- Receive study supplies and review study activities
- Sit and Stand importance.



Before Visit 3:

- Complete research homework as outlined above.
- **Must complete activities prior to Visit 3 or you are discontinued from study and must return TENS units.**

Research Homework after Visit 3:

- Complete home activities at days 30 and 60.
- **After day 60 research homework is completed, you will receive your 2 TENS units and complete a telehealth instruction on how to operate your units.**
- Complete research homework at days 65, 90 and 180.



Logging on to REDCap for Home Activities

Our data collection website is called REDCap. You will be sent a link to complete your home activities on day 1, 30, 60, 65, 90, and 180. Each time you click on the link, you will be able to complete your home activities with 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, rate pain and fatigue during the test

This is the type of link you will receive to log in to REDCap (it is just an example and does not work) <https://redcap.icts.uiowa.edu/redcap/surveys/?s=XX32XXLMGHM>

Research Homework – No TENS

The research homework you will complete is described below. The information you provide will be entered electronically by a tablet or computer. Below you will find a brief overview of your research homework.

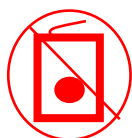
Your research homework will be completed at Day 1, 30, 60, 65, 90 and 180; all of these will be done with a window of time before and after each time point to allow for changes in your schedule.

The research homework include the following:



1. Log into the data collection site, called REDCap on a computer or tablet.

2. Research Homework Day 1, 30 and 60



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

3. Research Homework Day 65



– After your telehealth instruction you will do research homework with TENS.

- Rate your pain and fatigue at rest
- Complete sit and stand test and rate your pain and fatigue during the test.
- Begin a 30 minute TENS session
- After 30 minutes, rate your pain and fatigue at rest
- Repeat the sit and stand test and rate your pain and fatigue during the test

4. Research Homework Order Day 90 and 180

- 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

5. Use of TENS units

- Use TENS at home to your upper back and lower back for 2 hours per day, a minimum of 30 minutes at a time
- Use TENS units at each PT session during activity

- Use Quell Flex App **at least once per week**

PT Visit Patient Specific Functional Scale (PSFS)

As part of your PT evaluation at PT Clinic Visit 1, your therapist will ask you some questions about your activity limitations. They will ask you to give at least 2 activities and rate your ability to perform each activity. This will be repeated at days 30 and 60 if in physical therapy.

You will use the 0 to 10 scale below:

0=Unable to perform

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

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.

No TENS and TENS

We are excited to have you participate in the study!

Please make sure to call (319) 467-4203 or send an email to fmtips-studyteam@uiowa.edu if you have any questions.

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

Below is important information for you:

No TENS Days 1 through 60



- We are also interested to see how TENS changes how you feel when you start your own TENS use after 60 days.
- You will receive instruction on how to operate your TENS unit and electrodes during a telehealth visit with a study team member after day 60.
- Your participation in this group will help researchers and health care providers learn how TENS use helps those with pain from fibromyalgia and improve virtual instruction on the use of TENS.

TENS

When you begin your TENS treatments after 65 days:



- Our goal is to have you wear the TENS units on your neck and back for at least 2 hours per day, with a minimum of 30 minutes at a time. You have flexibility with how you make that happen. You can divide the time up or do it all at once. This means wearing the unit multiple times for 30 minutes or for 2 hours straight.
- We also ask that you wear the TENS unit during activity, and not while sitting or resting. If you are unable to wear the TENS unit for the full 2 hours or occasionally miss wearing the unit, we understand. Just do your very best.
- You may wear the units more than 2 hours per day.
- We ask that you log into the TENS smartphone app at least once a week to log your wearing time.

We want to know if the unit works to help people with fibromyalgia, but it is also important to know if there are things that make it difficult for people to wear such as getting the unit on/off or how you feel when it is on. TENS

TENS Contraindications and Precautions

A comprehensive list of contraindications and precautions can be found at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3031347/>

Contraindications for TENS

TENS is a safe, non-drug treatment for pain. There are few things to look out for when using your TENS unit. If you have any of the following items, please tell your physical therapists as this may impact your ability to participate.



- Implanted device like a pacemaker, cardioverter defibrillator, neurostimulator (brain or spinal cord), bone growth stimulator, indwelling monitors
- Cancer at site close to TENS use
- Pregnancy
- Epilepsy
- Thrombosis/thrombophlebitis
- Hemorrhage
- Recently radiated tissue
- Infection like osteomyelitis or tuberculosis

Precautions for TENS

Talk with your physical therapist or the study team if you have any of the following. They will be able to decide if you can participate based on your medical history.



- Pain of unknown origin
- Cancer at site remote to TENS use
- Cognitive impairments
- Cardiovascular disease

TENS Should Not Be Used Over the Following Areas



- Carotid sinus (front of the neck)
- Damaged skin
- Reproductive organs and genitalia
- Transcranial (across the brain)
- Across chest
- Eyes, mouth

Precautions Over the Following Body Regions or Conditions

Talk with your physical therapist or the study team if you have any of the following. They will be able to decide if you can participate based on your medical history.



- Extreme swelling
- Extreme adipose
- Visual impairment
- Impaired sensation
- Scar Tissue

TENS Use at Home



- We would like you to use your TENS units on your upper and lower back up to 2 hours a day. Please use the TENS units at a minimum of 30 minutes. You are welcome to break up the sessions through the day or do them all at once.
- You may wear the units more than 2 hours per day. Do what works for you.

TENS Use During PT Sessions



Please bring your TENS units and your supplies to your physical therapy sessions and use during activity. Please use the TENS units at a minimum of 30 minutes at each session. You may need to finish your TENS use after your PT session has ended.

Operating the TENS Unit



You will be given a separate booklet for operating your TENS units. Your TENS unit can be operated through a smart phone app or with the unit itself. If you have a question or a concern, please call or email the research study team.

Quell Flex Application (App)

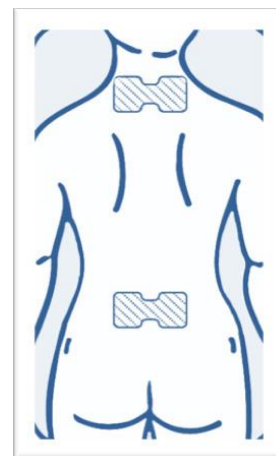


You will be given a separate booklet for the Quell Flex App. Please login to the application **at least once a week** to log your TENS wearing time.

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.

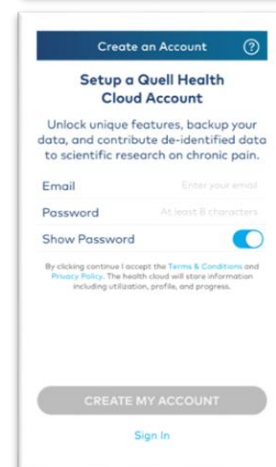
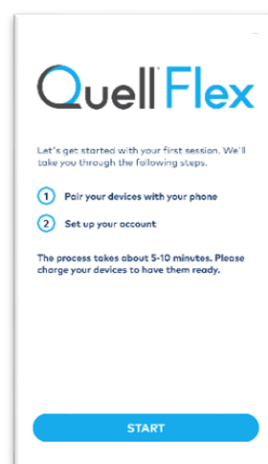


To end a treatment:

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 TIPSYXXXX@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!

Payment for Research Participation

As part of the study, you will receive TENS equipment for the study that you will be able to keep when the study is complete.



In addition, you will receive payment throughout the study as you complete your research homework with the payment schedule below:

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

If you have questions about payment, please contact the FM-TIPS research study team.

Frequently Asked Questions in the Study

1. Can I end my participation in the study any time I want to?

Yes, just let us know by calling or emailing the research study team.

2. What do I do with my TENS unit if I end my participation?

If you have not completed any research homework (sit and stand test or questionnaires), or if you decide not to participate in the study, please return the TENS units to your Physical Therapist.

3. What is a TENS unit?

A transcutaneous electrical nerve stimulation (TENS) unit is a battery-operated device that can be used to treat pain. TENS works by delivering small electrical impulses through electrodes applied to a person's skin.

4. How does TENS reduce pain?

TENS is a non-drug treatment that delivers a safe electrical current to your body. The electrodes that are placed on your skin send electrical impulses to nerve pathways. TENS releases chemicals in your body that stop pain signals and helps to reduce pain and fatigue during movement. There is no risk of dependency or addiction.

5. Will there be any additional cost to me for participating in the study?

No, there will be no extra cost to you, and you will receive the TENS unit and a supply of electrodes for free.

6. What happens if I become sick or injured during my participation in the study?

You should contact your physical therapist and the study team as soon as possible to determine if it is safe for you to continue in the study.

7. What happens if I find out I am pregnant during my participation in the study?

You should stop using the TENS unit immediately and contact the research study team.

8. Can I take all of my normal medications while using a TENS unit?

Yes.

9. Can I continue other treatments while using a TENS unit, i.e. acupuncture?

Yes.

10. Will my individual information from the study be shared?

No, all results from the study will be de-identified.

11. What are the risks associated with TENS treatment?

You may experience local skin irritation (caused by the adhesive in the TENS electrode pad), mild redness at the site of the TENS stimulation, a burning or pricking sensation if insufficient electrode gel is present, or discomfort or aggravation of pain from TENS.

12. Will using a TENS unit restrict my activities?

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

13. What are the alternative options if I choose not to do this study?

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

14. How do I contact the study staff if I have questions or concerns?

If you have any questions about the research study itself, please contact: Dr. Dana Dailey or Dr. Kathleen Sluka 319-467-4203.

If you experience a research-related injury, please contact: Dr. Dana Dailey or Dr. Kathleen Sluka 319-467-4203.

Completing the Study



Congratulations! You have successfully completed the FM-TIPS study. We sincerely thank you for sticking with us for the full 6 months.



The TENS units and any electrodes you have left are yours to keep. When you need more electrodes please contact the manufacturer, Quell, using the contact information provided



Your final check will be in the mail soon. Your last research homework entered into the REDCap database automatically started the payment process. Please let us know if you do not receive the check within four weeks of completion of the study.



Research is an important process in developing new treatments. The fibromyalgia community will directly benefit from your participation in this study.

Thank you!
FM-TIPS Study Team



Quell Flex

App User Manual

Getting Started with the Quell Flex App

Downloading the Quell Flex App

Using your mobile device or tablet, open the App Store or Google Play. Search “Quell Flex” by NeuroMetrix and download the app to your device. Ensure that your device’s Bluetooth is turned on and that your device is running iOS 10 or later, or Android 6 or later. Launch the Quell Flex App and follow the step by step instruction within the app to pair and setup a Quell Health Cloud account while charging your device.



Preparing for Therapy Session

Before starting a therapy session, hook the lead wires into the electrodes and place electrodes on your upper and lower back, and then connect the devices to the electrodes corresponding color-coded wire to the “upper” and “lower” back. You should also check the battery to ensure it has an adequate charge. If the indicator light on top of the unit blinks white, you have sufficient charge to run a therapy session.

START

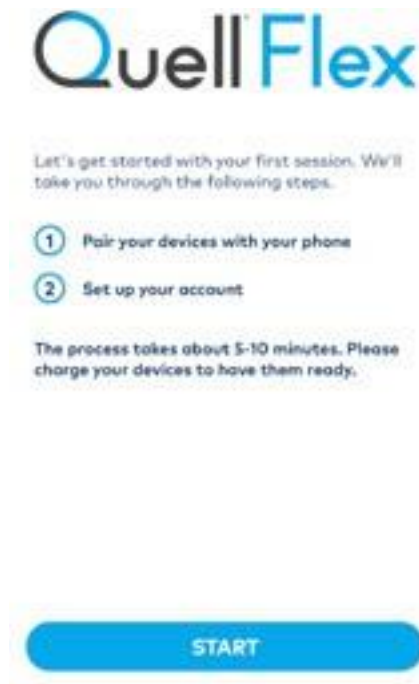
1

2

Getting Started with the Quell Flex App

Instructions within the app will guide you through two steps:

1. Pair your devices with the phone
2. Set up your account



START

Pair your Device with the Phone (mobile device or tablet)

You will pair both the “Upper” and “Lower” Quell Flex TENS units. Once you enter the last two digits the device will recognize your Quell Unit as either “Upper” or “Lower.”



START

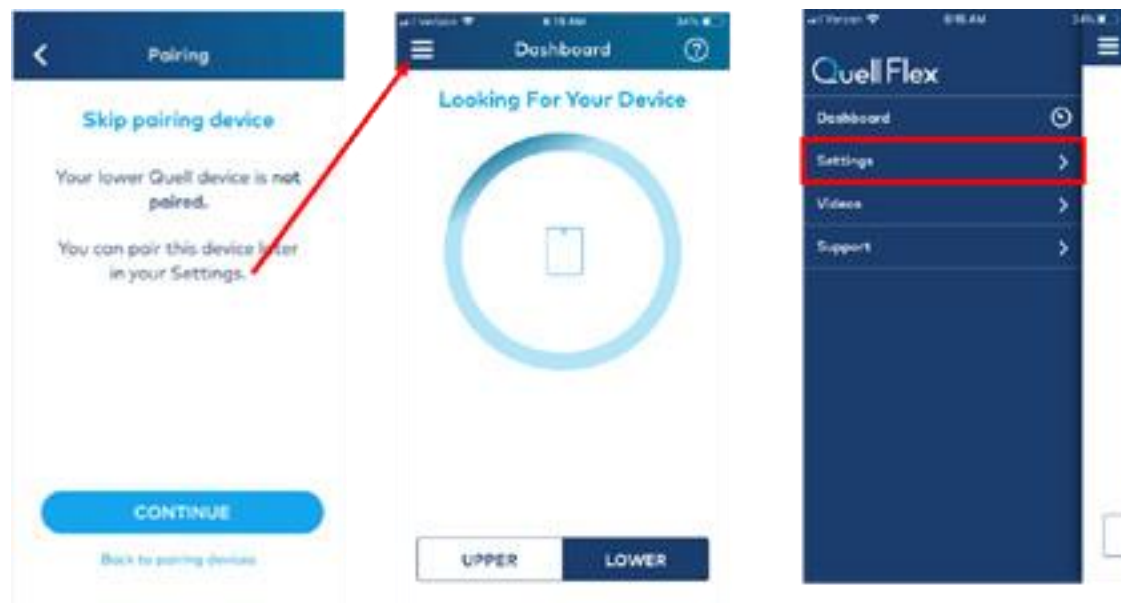
Pair your Device with the Phone (mobile device or tablet)

The app will then guide you through the process to pair your second Quell Unit.



START

If one of your Quell Flex TENS units is not fully charged, then you can proceed with your treatment using only one unit and use the second at a later time. To pair the unit later, then click on the 3 horizontal bars in the upper left to access 'Settings'. Then you can pair your second device following the instructions as indicated above.



START

5

6

Creating a Health Cloud Account

Onboarding with the Quell Flex App

Thanks to people like you, FM-TIPS is examining the effects of consistent TENS use on pain and fatigue for individuals with fibromyalgia. In order to capture your TENS use, it is important that you properly set-up your account:

1. 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
2. Password: **dailytens**



ACCOUNT

The following instructions expand upon the setup instructions provided within the Quell Flex App.

Starting a Therapy Session

To start a TENS session, tap the Start Therapy button on the Dashboard screen in the app. The indicator light on the unit will blink white for the duration of the therapy session.



Adjusting Intensity During a Therapy Session

Frequent adjustments should not be necessary; however, if the sensation feels uncomfortable or is not strong enough, you may make adjustments. To adjust therapy intensity or to stop therapy, tap the “+/-” buttons on the Dashboard screen in the smartphone app. You want to stimulation to remain **strong but comfortable**.

Ending a Therapy Session

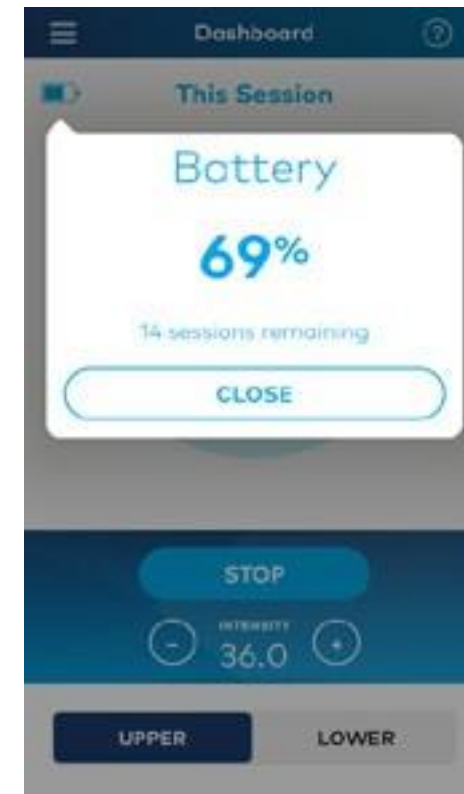
Regular therapy sessions will run automatically 60 minutes on, then 60 minutes off, unless you turn off therapy during a session or recalibrate between therapy sessions.

To stop an active therapy session before it ends, tap the STOP button on the Dashboard screen in the app. If the app is not readily accessible, you can manually stop therapy during a session by firmly tapping the blue button four times in a row with your finger. You should not remove the device while it is stimulating, so make sure that the white indicator light is not blinking before removing the device and electrode from your back. Otherwise you may experience an uncomfortable sensation while removing the device.



Checking the battery level

In order to check the charge level of the battery in each TENS unit, touch the battery icon in the upper left corner.



Contact Information

STUDY TEAM



App

App Store or Google Play. Search “Quell Flex” by NeuroMetrix



Email

fmtips-studyteam@uiowa.edu



Website

www.fmtips.org



Phone

(319) 467-4203



Address

UI PHYSICAL THERAPY, 1-248 MEB, 500 Newton Rd,
Iowa City, 52242

TENS UNIT MANUFACTURER

Quell

4B Gill Street

Woburn, MA 01801

1-800-204-6577

customercare@quellrelief.com

Customer Care Hours:

9am to 6pm Eastern Standard Time

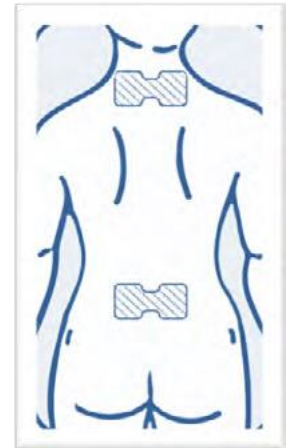
Monday – Friday

Except major holidays

FM-TIPS 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.

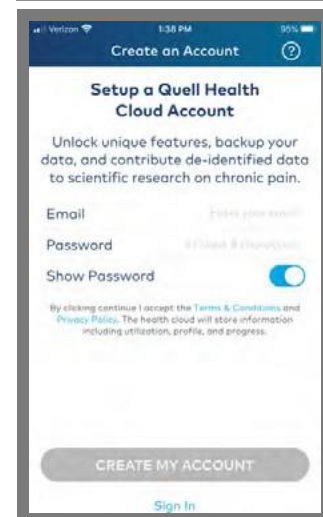


To end a treatment:

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 Smartphone Application:

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 site YY**) to **TIPSYXXXX@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 per week.**



For complete FM TIPS Quell Flex instructions, please refer to your participant manuals!

TENS

Transcutaneous Electrical Nerve Stimulation



FM-TIPS

Fibromyalgia TENS In
Physical Therapy Study

How Does TENS Work?

Transcutaneous Electrical Nerve Stimulation (TENS) therapy is used in physical therapy settings to decrease pain. Electrodes placed on the skin deliver electrical impulses to the tissues below activating nerve pathways . TENS stimulation releases chemicals in your body that stop pain signals. The electrode patches are controlled by a small unit that is worn on the belt or carried in a pocket. The intensity of the stimulation is set by the user.

What Is TENS Used For?

TENS helps reduce pain during movement. An important benefit of TENS for chronic pain conditions is that it is a non-pharmacologic treatment. Medication dependency

or addiction is not a risk for patients.

When Is It Best To Use TENS?

Research has shown that TENS is most helpful for chronic pain when used for at least 30 minutes while you are active. It is less effective when you are sitting still, lying down, or resting.

Do Not Use TENS If You Have:

- A cardiac pacemaker or defibrillator
- A spinal cord stimulator
- In-dwelling pumps or monitors
- Any implanted metallic or electronic device
- Active Cancer
- Epilepsy
- Pregnant or planning on becoming pregnant in the next six months

Contact the study team if:

- You have problems with the TENS units or electrode patches.
- You have an allergic response to adhesives or skin irritation with TENS.

TENS Safety

- Do not use TENS on:
 - » Open wounds or rashes
 - » Swollen, red, infected, or inflamed skin
 - » Cancerous lesions, or close to them
 - » Skin that does not have normal sensation (feeling)
 - » Any part of your head or face
 - » Any part of your throat
 - » Both sides of the chest or trunk at the same time
 - » Directly on your backbone
- Do not use TENS while:
 - » Bathing or showering
 - » Sleeping
 - » Driving
 - » Using machinery
- Turn the TENS unit **OFF** before you put on, move, or take off the electrode patches. **DO NOT** share your electrode patches with other people.
- Only use the TENS unit on yourself as instructed.
- Keep out of reach of children.
- Electronic equipment, such as EKG monitors and EKG alarms, may not work correctly when TENS is in use.

How To Use The TENS Unit

Your TENS works by delivering an electrical current through wires and electrode patches.

Your package should have:

- 2 TENS units. One is **purple** and marked “upper” and the other is **orange** and marked “lower”
- Electrode patches
- 2 wall chargers
- Pouch belt clip
- Quell Flex Quick start guide

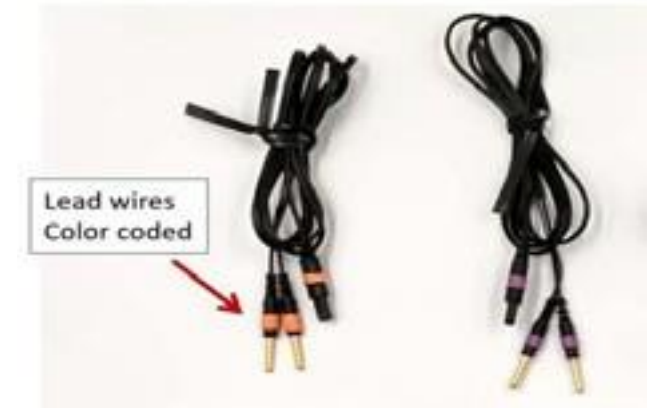


To Start Treatment

Make sure the skin of your upper back and lower back is clean (clean off oil/lotion) and dry. It is very important to put the electrode patches on clean, dry skin so they make firm contact. If the patch is not secure, changes in the stimulation may happen, which could cause discomfort.

- Make sure the TENS unit are OFF.
- Charge each unit, the charger port is on the side of the unit. A full charge will take 1.5-2 hours.
- Remove the unit from the charger to begin a treatment.
- Never proceed with a TENS treatment while the unit is plugged into the wall charger.
- Take the electrode patches out of their plastic storage bag. Save the bag for future storage.
- Put the lead wires all the way into the connector on each patch.
- Make sure there are NO bare metal pins exposed.
- Take the electrode patches off the plastic liner. Save the liner for future storage.
- Place the electrode patches on your clean, dry skin.

- See the pictures on the next pages to learn where to place the electrode patches.
- There are 2 electrode patches that must be placed on the body.
- The electrode patches should not touch each other or any metal object, such as a belt buckle or metal jewelry.
- Plug the color-coded lead wire into the matching color unit. **Purple** for upper back, **orange** for lower back
- Turn the unit ON by pressing the blue button on the front
- A white light flashing on the top of the TENS unit indicates that the unit is on. (two quick flashes)

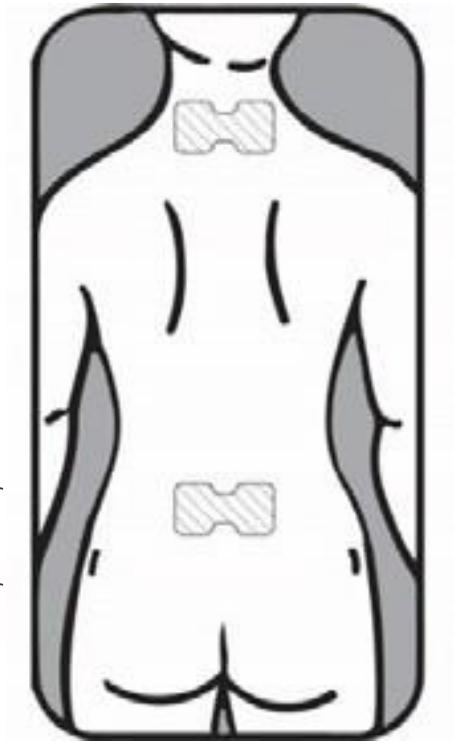


- To increase intensity, press and hold the blue button.
- Increase the intensity to be strong but comfortable.
- This may cause your muscles to contract.
- The first time that you use the unit you will have to increase the intensity from zero to a strong, comfortable intensity. After the initial period, it may be necessary for you to increase or decrease the intensity.
- The intensity should be a strong, comfortable, non-painful sensation.
- After a few minutes, it may seem the stimulation has gone down. This is normal as your body gets used to the TENS. You should turn up the intensity to keep it feeling strong.
- To decrease the intensity, press and release the blue button. Wait a few seconds and press and release again to decrease further.
- You will notice that an abbreviated version of these on/off and intensity instructions are printed on the front of each unit.

Placement of the Electrode Patches



Image
Courtesy of
Compass
Health Brands
AccuRelief
TENS products
www.
accurelief.com



To Stop Treatment

1. Press the blue button 4 times in a row to stop the treatment. The white light on top of the TENS unit will be off. Make sure the TENS unit is turned OFF before removing the electrodes.
2. Carefully take the lead wires out of the electrode patches.
 - Pulling or yanking on the wires could damage the wires or electrode patches.
3. You may either take off the electrode patches from your skin or leave them on until your next use if you are going to use it again.
 - If you take off the electrode patches, use the white strip in the middle that is not sticky and gently peel them off your skin and place them back onto the plastic liner.

4. Put the liner and electrode patches in the plastic storage bag and store it in a cool, dry place until you use them again.
5. You may leave the color-coded lead wires attached to the unit or carefully remove them by pulling at the very base where there is a hard-plastic section that has the color-coded ring on it.
6. Do not pull on the wires for removal.

Tips for Use

- The electrode patches can be used over and over, until the adhesive wears out.
 - » The electrode patches will stay sticky and last longer if you clean your skin before you start and put them back in the storage bags when you are done.
 - » Electrode patches can dry out if left out of the storage bags too long.

- Electrode patches that are dirty and/or hard to attach can be washed softly with your fingertips for 10 seconds using slow-running, cold water and air-dried.
- 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.
- Recharge the unit when the white light is not displayed when you try to turn the unit on. You can also check the battery life in the Quell Flex App.
- Attach a belt clip or the Quell Flex pouch to the TENS unit to use it hands-free while you are active.



Preventative Maintenance

- Do not drop the unit on hard surfaces, get it wet, or leave it in very hot or very cold places.
- Do not bend or coil the lead wires tightly. This can damage them.

Cleaning and Storage

- To clean the unit, turn it off and take the lead wires out of the electrode patches. Gently wipe the unit with a slightly moistened, soft cloth.
 - » Do not use chemical cleaners.
 - » Do not use rubbing alcohol.
 - » Do not let water get inside the unit.
- Store the unit and wires in a cool, dry place when you are not using it.

Problem: Cannot Feel The Current

- Turn the unit OFF before making changes.
- Check the power source.
 - » Does the unit light come on when start is pressed?
 - » Is the unit charged?
- Check the electrode patches.
 - » Are they all sticking on the body? *(a yellow flashing light may replace the white light if this is the problem)*
 - » You may be able to reactivate the sticky surface. Wet your fingertip with water and gently rub the patch surface for 10 seconds. Let it dry for 60 seconds and try putting it on again. If this does not work, use new electrode patches.
- Check the wires.
 - » Are they plugged into both the patch and unit properly?

Problem: No Pain Relief

- If you have not tried this, turn up the intensity to keep the feeling strong but comfortable.
- Try changing the position of the electrode patches. Anywhere in your neck or back is acceptable, you should always allow at least 5 inches between electrode patches.
- Call the study care team for help.

Problem: Skin Irritation

- Call the study team if you have redness, a rash, or itching in the first 24 hours of use.
- Move the electrode patches to a different site as outlined above Do not put them on broken or irritated skin.
- Clean your skin and let it air dry before putting on the electrode patches.

Problem: Electrode Patches Will Not Stay On Or In Place

- Try to reactivate the sticky surface. Wet your fingertip with water and gently rub the patch surface for 10 seconds. Let it dry for 60 seconds and try putting it on again.
- Try using a skin prep product. This product is put on the skin before placing the patch. It helps the electrode patches stick better. You can buy it online or at a medical supply store.
- Sweating can cause the electrode patches to move out of place. If this happens often and a skin prep product does not help, try to hold the electrode patches in place with medical tape. Ask the study team for instructions.

Frequently Asked Questions

- What does TENS feel like?
 - » *You may feel tingling, tapping, buzzing, or muscle twitching. You may also notice the TENS feels stronger or weaker at times. You may become used to the feeling and can turn up the intensity as you wear it longer.*

- Does it hurt?
 - » *No, it should not hurt. Make sure you are setting it at a strong but comfortable intensity.*
- Can TENS harm my body?
 - » *No, but in a small number of people it can cause some skin irritation from the electrode patches.*

- Can I get shocked?

The TENS unit gives a therapeutic dose of electricity to your body. The higher you turn it up, the more intense the feeling will be and the more pain relief you will get. Turning it up as high as it will go may cause surprise and discomfort, but it will not harm you.

- » *Since the unit is an electrical device, you can get shocked if:*
 - | *You reposition, or take off, the electrode patches or if you remove the wires from the electrode patches without first turning the unit off.*
 - | *The unit gets wet while you are using it.*
 - | *You touch bare wires on a damaged cord.*

- Can I do a treatment while the unit is on the wall charger?
 - » *NO. The unit is NOT designed to deliver treatment while it is connected to the wall charger.*
- What if a wire comes out of the unit or electrode patches?
 - » *Turn the unit OFF put the wire back in, and restart the unit.*
- Does it matter where I place the electrode patches?
 - » *Yes! Place them on fleshy areas of the back, not over boney sites.*
 - » *Yes! Since the purpose of this study is to test neck and back pain specifically, wear the electrode patches on the upper and lower back as described by your physical therapist. Once the study is over, you may place the electrode patches on other locations of the body.*
- What if the electrode patches fall off?
 - » *Turn the unit OFF and take the wire out of the patch. You can either clean and dry the patch or replace it with a new patch. In either case, make sure your skin is clean and dry before putting on the patch and restarting the unit.*

- Is it OK if my muscles twitch?
 - » *Yes, as long as it is not uncomfortable. Having your muscles twitch for longer than 30 minutes may cause them to get tired or sore.*
- Is it OK to keep the stimulation so that I just barely feel it?
 - » *No. Research shows this will not provide pain relief.*
- What if the electrode patch falls off?
 - » *Try cleaning your skin, wetting the gel or using skin prep as instructed. If these are not successful, try a new electrode. If you still have problems, contact the study team.*
- What do the different flashing lights on the top of the unit mean?
 - » *A single white flashing light means the unit has sufficient charge to begin a treatment when you turn the unit on.*
 - » *A double white flashing light occurs when you begin a treatment by increasing the stimulation intensity. The lights will flash during each treatment session.*

- » *A yellow light 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.*
- Why do I not wear it to bed?
 - » *It is easy for the wires to get tangled or unplugged, or the electrode patches may come off. Not wearing it to bed also lets your skin rest from wearing the electrode patches.*
- Why can't I let someone else try my TENS unit?
 - » *Just as you would not let others take a medicine that was only prescribed for you, you should not let others use your TENS unit. Also, we are collecting TENS use information with the Quell Flex App and the data should represent only your use of the units.*
- How can I get the pouch holding the TENS units to stay more securely on my waistband during activity?
 - » *In addition to the plastic clip on the pouch, you can add another clip (binder clip, bag clip, paperclip) to create a second point of attachment to your waistband. The bag*

- » *also has a piece of Velcro and a drawstring that can attach/tie around a belt loop to keep the bag more fixed to your waistband during activity..*
- What is the problem with wearing it in the shower?
 - » *There is a chance for electrical shock since it is an electrical device. Also, the unit is not waterproof and would be damaged.*
- Do I have to use both electrode patches?
 - » *For the purposes of this study you should wear both electrode patches as often as possible. You will get more stimulation, which could give you greater pain relief.*
- Where do I get more electrode patches?
 - » *You will receive your first 10 electrodes with your unit. Electrodes are designed to last up to first two months. After that, we will send you additional electrodes in the mail.*
- Does insurance cover a TENS unit?
 - » *TENS units are not routinely covered by insurance, but all companies have different policies. Please call your insurance company to find out if your plan covers a TENS unit.*

Contact Information

STUDY TEAM



App

App Store or Google Play. Search “Quell Flex” by NeuroMetrix



Email

fmtips-studyteam@uiowa.edu



Website

www.fmtips.org



Phone

(319) 467-4203



Address

UI PHYSICAL THERAPY, 1-248 MEB, 500 Newton Rd,
Iowa City, 52242

TENS UNIT MANUFACTURER

Quell

4B Gill Street

Woburn, MA 01801

1-800-204-6577

customer@quellrelief.com

Customer Care Hours:

9am to 6pm Eastern Standard Time

Monday – Friday

Except major holidays

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 are 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.



FM-TIPS

*Fibromyalgia TENS In
Physical Therapy Study*

National Institutes of Health Funded Pragmatic Clinical Trial



TENS

Participant Manual

V2.0 6/4/2021

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Welcome to the FM-TIPS Study!

Thank you for participating in 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) between 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 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
- TENS Instruction
- 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

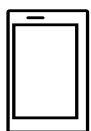
Study Team



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

How to 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
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Iowa City, IA 52242

Study Overview

- This is a clinical trial funded by the National Institutes of Health (NIH), Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).
- We are using a pragmatic (real-world) clinical trial design. A pragmatic trial tests a treatment in a real clinical setting.

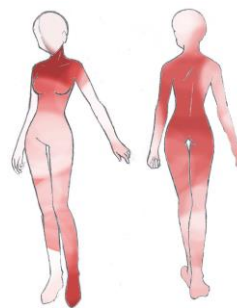


- Movement pain related to fibromyalgia interferes with physical therapy exercises and daily activities.
- Transcutaneous Electrical Nerve Stimulation (TENS) is a safe and effective treatment for movement-evoked pain and fatigue for individuals with fibromyalgia (Dailey, et al. 2019; <https://onlinelibrary.wiley.com/doi/full/10.1002/art.41170>).
- TENS is underutilized by physical therapists and other health professionals for the treatment of chronic pain.
- The goal of this trial is to test if TENS with physical therapy decreases movement-evoked pain and improves function and participation compared to physical therapy alone for individuals with fibromyalgia.

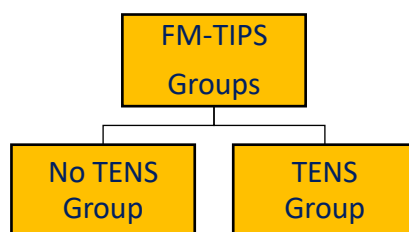


Study Design

- To be included in the FM-TIPS study
 - You must have a diagnosis of fibromyalgia from your physician.
 - You must be coming to physical therapy for fibromyalgia OR neck pain or back pain and have a diagnosis of fibromyalgia.



- There are two participant groups in the FM-TIPS study: No TENS or TENS.



Study Participants - TENS

- You are attending a physical therapy clinic that has been designated for TENS.
- Your group is a very important group in the study. You will help us know how TENS can help to reduce pain, increase adherence to physical therapy, reach personal functional goals, and decrease drug use. We could not do the study without you!
- You will receive 2 TENS units to use at home and during PT appointments. Your PT will provide instructions on how to use the TENS device. The study will last for 6 months. You will keep these units when the study is over.
- Your physical therapist will provide standard treatment and guide you with instruction of study-related activities along the way.



Requirements of participating in the study:



- You will complete research homework that includes answering several questionnaires and doing a sit and stand test. The study activities will take about 45 minutes.



- The study requires doing research homework over 6 months.
- Schedule of research homework - Day: 1, 30, 60, 90 and 180.



- Two TENS devices and supplies and up to \$200 will be awarded to you for completing activities during the study.

Participation in the study is not required to continue with your physical therapy care. However, you will not be enrolled in the study if you decline to participate.

Timing of Research Homework - TENS

TENS Participant Research Homework



PT Visits 1-3 Overview - TENS

Visit 1:

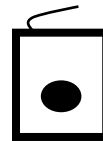
- Complete eligibility pre-screening on tablet in clinic
- Patient Specific Functional Scale with Physical Therapist

Before Visit 2:

- Review and complete informed consent form, called eConsent. This is **required to be enrolled and begin participation** in the study.

Visit 2:

- Receive TENS study supplies and instructions on use.
- Sit and Stand importance

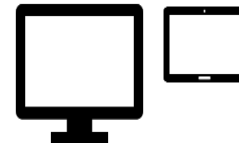


Before Visit 3:

- Complete research homework as outlined above
- **Must complete activities prior to Visit 3 or you are discontinued from study and must return TENS units**

Research homework after Visit 3:

- Complete research homework 30, 60, 90, and 180 days



Logging on to REDCap for Research Homework

Our data collection website is called REDCap. You will be sent a link to complete your research homework on day 1, 30, 60, 90, and 180. Each time you click on the link, you will be able to complete your research homework with 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
- 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

This is the type of link you will receive to log in to REDCap (it is just an example and does not work) <https://redcap.icts.uiowa.edu/redcap/surveys/?s=XX32XXLMGHM>

Research Homework - TENS

The research homework you will complete is described below. The information you provide will be entered electronically on a tablet or computer. Below you will find a brief overview of your research homework.

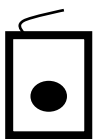
Your research homework for data collection will be completed at Day 1, 30, 60, 90 and 180; all of these will be done with a 5-day window to allow for changes in your schedule (± 5 days).

The research homework will include the following:

1. Log into the data collection site, called REDCap on a computer or tablet
2. Use of TENS units for pain relief for the study
3. Research Homework order
 - 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



4. Use of TENS units



- Use TENS at home to your upper back and lower back for 2 hours per day, a minimum of 30 minutes at a time
- Use TENS use at each PT session during activity
- Use Quell Flex App **at least once per week**

Patient Specific Functional Scale (PSFS)

As part of your PT evaluation at PT Clinic Visit 1, your therapist will ask you some questions about your activity limitations. They will ask you to give at least 2 activities and rate your ability to perform each activity. This will be repeated at days 30 and 60 if you are still in physical therapy.

You will use the 0 to 10 scale below:

0=Unable to perform

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

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 are 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

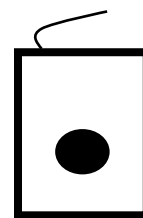
We are excited to have you participate in the study!

Please make sure to call (319) 467-4203 or send an email to fmtips-studyteam@uiowa.edu if you have any questions.

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

Below is important information for TENS:

- Our goal is to have you wear the TENS units on your neck and back for at least 2 hours per day, with a minimum of 30 minutes at a time. You have flexibility with how you make that happen. You can divide the time up or do it all at once. This means wearing the unit multiple times for 30 minutes or for 2 hours straight.
- You may wear the units more than 2 hours per day. Do what works for you. We also ask that you wear the TENS units during activity, and not while sitting or resting. If you are unable to wear the TENS units for the full 2 hours or occasionally miss wearing the unit, we understand. Just do your very best.
- We ask that you log into the Quell Flex App **at least once a week to log your wearing time.**



We want to know if the unit works to help people with fibromyalgia, but it is also important to know if there are things that make it difficult for people to wear such as getting the unit on/off or how you feel when it is on.

TENS Contraindications and Precautions

A comprehensive list of contraindications and precautions can be found at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3031347/>

Contraindications for TENS

TENS is a safe, non-drug treatment for pain. There are few things to look out for when using your TENS unit. If you have any of the following items, please tell your physical therapists as this may impact your ability to participate.



- Implanted device like a pacemaker, cardioverter defibrillator, neurostimulator (brain or spinal cord), bone growth stimulator, indwelling monitors
- Cancer at site close to TENS use
- Pregnancy
- Epilepsy
- Thrombosis/thrombophlebitis
- Hemorrhage
- Recently radiated tissue
- Infection like osteomyelitis or tuberculosis

Precautions for TENS

Talk with your physical therapist or the study team if you have any of the following. They will be able to decide if you can participate based on your medical history.



- Pain of unknown origin
- Cancer at site remote to TENS use
- Cognitive impairments
- Cardiovascular disease

TENS Should Not Be Used Over the Following Areas



- Carotid sinus (front of the neck)
- Damaged skin
- Reproductive organs and genitalia
- Transcranial (across the brain)
- Across chest
- Eyes, mouth

Precautions Over the Following Body Regions or Conditions

Talk with your physical therapist or the study team if you have any of the following. They will be able to decide if you can participate based on your medical history.



- Extreme swelling
- Extreme adipose
- Visual impairment
- Impaired sensation
- Scar Tissue

TENS Use at Home



- We would like you to use your TENS units on your upper and lower back for at least 2 hours a day. Please use the TENS units at a minimum of 30 minutes at a time. You are welcome to break up the sessions through the day or do them all at once.
- You may wear the units more than 2 hours per day. Do what works for you.

TENS Use During PT Sessions



Please bring your TENS units and your supplies to your physical therapy sessions and use during activity. Please use the TENS units at a minimum of 30 minutes at each session. You may need to finish your TENS use after your PT session has ended.

Operating the TENS Units



You will be given a separate booklet for operating your TENS units. Your TENS unit can be operated through a smart phone app or with the unit itself. If you have a question or a concern, please call or email the research study team.

Quell Flex Application (App)

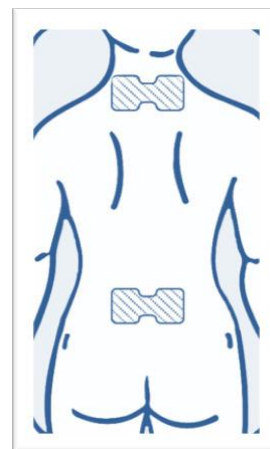


You will be given a separate booklet for the Quell Flex App. Please login to the application **at least once a week** to log your TENS wearing time.

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.

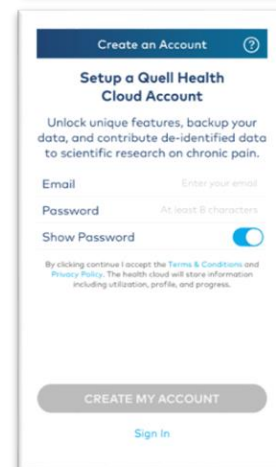
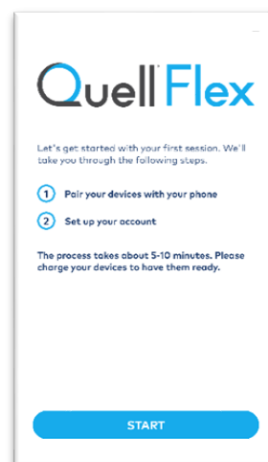


To end a treatment:

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 TIPSYXXXX@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!

Payment for Research Participation

As part of the study, you will receive TENS equipment for the study that you will be able to keep when the study is complete.



In addition, you will receive payment throughout the study as you complete your research homework with the payment schedule below:

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

If you have questions about payment, please contact the FM-TIPS research study team.

Frequently Asked Questions in the Study

1. Can I end my participation in the study any time I want to?

Yes, just let us know by calling or emailing the research study team.

2. What do I do with my TENS unit if I end my participation?

If you have not completed any research homework (sit and stand test or questionnaires), or if you decide not to participate in the study, please return the TENS units to your Physical Therapist.

3. What is a TENS unit?

A transcutaneous electrical nerve stimulation (TENS) unit is a battery-operated device that can be used to treat pain. TENS works by delivering small electrical impulses through electrodes applied to a person's skin.

4. How does TENS reduce pain?

TENS is a non-drug treatment that delivers a safe electrical current to your body. The electrodes that are placed on your skin send electrical impulses to nerve pathways. TENS releases chemicals in your body that stop pain signals and helps to reduce pain and fatigue during movement. There is no risk of dependency or addiction.

5. Will there be any additional cost to me for participating in the study?

No, there will be no extra cost to you, and you will receive the TENS unit and a supply of electrodes for free.

6. What happens if I become sick or injured during my participation in the study?

You should contact your physical therapist and the study team as soon as possible to determine if it is safe for you to continue in the study.

7. What happens if I find out I am pregnant during my participation in the study?

You should stop using the TENS unit immediately and contact the research study team.

8. Can I take all of my normal medications while using a TENS unit?

Yes.

9. Can I continue other treatments while using a TENS unit, i.e. acupuncture?

Yes.

10. Will my individual information from the study be shared?

No, all results from the study will be de-identified.

11. What are the risks associated with TENS treatment?

You may experience local skin irritation (caused by the adhesive in the TENS electrode pad), mild redness at the site of the TENS stimulation, a burning or pricking sensation if insufficient electrode gel is present, or discomfort or aggravation of pain from TENS.

12. Will using a TENS unit restrict my activities?

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

13. What are the alternative options if I choose not to do this study?

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

14. How do I contact the study staff if I have questions or concerns?

If you have any questions about the research study itself, please contact: Dr. Dana Dailey or Dr. Kathleen Sluka 319-467-4203.

If you experience a research-related injury, please contact: Dr. Dana Dailey or Dr. Kathleen Sluka 319-467-4203.

Completing the Study



Congratulations! You have successfully completed the FM-TIPS study. We sincerely thank you for sticking with us for the full 6 months.



The TENS units and any electrodes you have left are yours to keep. When you need more electrodes please contact the manufacturer, Quell, using the contact information provided



Your final check will be in the mail soon. Your last research homework entered into the REDCap database automatically started the payment process. Please let us know if you do not receive the check within four weeks of completion of the study.



Research is an important process in developing new treatments. The fibromyalgia community will directly benefit from your participation in this study.

Thank you!
FM-TIPS Study Team