

# Can electrical stimulation using a TENS device improve recovery from a sprained ankle when added to therapeutic stretching?

<b>Submission date</b> 28/11/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/12/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/05/2022	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A sprained ankle is when the ankle joint has moved out of its normal range of movement causing one of the ligaments (bands of tissue that connect bones) to become stretched or torn. This can cause pain and reduces the ability to walk or participate in sports. Ankle sprains are very common injuries and can take weeks or months to heal depending on the severity.

Proprioceptive neuromuscular facilitation (PNF) stretching is a technique for treating injuries of muscles, bones and joints where a person stretches a muscle while pushing against resistance provided by a therapist. This technique is widely used and has been shown to improve the range of motion of sprained ankles.

Transcutaneous electrical nerve stimulation (TENS) uses electrodes placed on the skin to deliver an electric current to stimulate nerves. It is thought to reduce pain.

There is not much research on whether TENS in combination with PNF stretching is more effective than PNF stretching alone. This study aims to investigate this in adults who still have problems resulting from an ankle sprain at least 3 months previously.

### Who can participate?

Men aged 18 to 40 years who sprained their ankle at least 3 months previously and are not able to bend their foot upwards on the injured leg as much as on the uninjured leg.

### What does the study involve?

The participants will be randomly allocated into three groups. Two groups will receive 3 weeks of treatment, with four sessions of PNF stretching each week. One group will have TENS treatment at the same time as the PNF stretching. All three groups will be assessed for pain, range of movement, ankle position feeling, calf flexibility, balance and muscle strength before and after the treatment.

### What are the possible benefits and risks of participating?

All participants will receive treatment for their sprain and those receiving TENS might experience reduced pain or a faster recovery. The TENS machine will be adjusted so that it is not delivering a painful electrical current. The investigators do not expect any risks to participants.

Where is the study run from?  
King Khalid University (Saudi Arabia)

When is the study starting and how long is it expected to run for?  
August 2019 to April 2020

Who is funding the study?  
The investigator is funding the study.

Who is the main contact?  
Dr Paul Silvian, pslvin@kku.edu.sa

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
Nil known

## Study information

**Scientific Title**  
Effectiveness of low frequency stimulation in proprioceptive neuromuscular facilitation techniques for balance and proprioception in post ankle sprain adults

**Acronym**  
Electrical Stimulation and proprioception fo ankle sprain

## **Study objectives**

Current study hypothesis as of 14/04/2020:

1. To compare the baseline, post and follow-up effect between proprioceptive neuromuscular facilitation (PNF) stretching technique combined with electrostimulation (TENS) and proprioceptive neuromuscular facilitation (PNF) stretching technique.
2. To determine the treatment effect between the groups for pain, physical activity, balance, flexibility, proprioception, and muscle strength

Previous study hypothesis as of 24/03/2020:

1. To determine whether calf muscle flexibility improves with proprioceptive neuromuscular facilitation (PNF) stretching alone or combined with electrical stimulation
2. To determine the physical activity levels related to flexibility, proprioception, balance, and strength for post ankle sprained subjects

Previous study hypothesis:

To determine whether calf muscle flexibility improves with proprioceptive neuromuscular facilitation (PNF) stretching alone or combined with electrical stimulation.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 30/10/2019, King Khalid University Research Ethics Committee (Deanship of Scientific Research, C/3/108, Guraiger, Abha 62529, Saudi Arabia; +966 17 241 8667; ecm@kku.edu.sa), ref: ECM#2019-26, HAPO-06-B-001)

## **Study design**

Randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Recovery following ankle sprain

## **Interventions**

Current interventions as of 14/04/2020:

Subjects will be randomly allocated into three groups using a block randomization method using <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. Each group needs 20 subjects so each block will have 20 subjects with 3 blocks.

Pre-testing will be done for all the primary and secondary outcome measures by an independent evaluator who is not involved with the subject's treatment.

1. Calf flexibility measured using the knee to wall test
2. Range of motion for ankle joint dorsiflexion and plantar flexion
3. Ankle proprioception

4. Dynamic balance assessed using the star excursion balance test
5. Muscle strength - ankle dorsiflexors and plantar flexors
6. Pain sensation was measured using a visual analog scale (VAS).

After the evaluation, the subjects will be provided treatment as per their group protocol.

Group 1: Experimental group 1 (treatment involved)

Physical Therapy proprioceptive neuromuscular Facilitation (PNF) + electrical stimulation device (TENS): In this group, the total intervention will be for a half hour. The therapist will strictly follow the fundamental principles of the PNF method in terms of manual contact, body position and body mechanics, verbal commands and vision. The PNF stretching protocol will be carried out as previously described (for the control group), along with (TENS) electrical stimulation using a TENS unit. Two electrodes (4 x 8 cm) will be placed 5 cm apart on the calf muscle, and 2 electrodes (5 x 5 cm) placed just distal to the popliteal fossa and the other 5 cm distal to the proximal electrode on the muscle. The electrostimulation unit will deliver a biphasic current using a symmetrical waveform at 5 Hz for 15 s. Intensity will be set to the maximum tolerated by each participant. The participants will undergo the hold-relax PNF technique along with the electrical stimulation protocol on the affected lower limb 4 times in each session.

Group 2: Experimental group 2 (treatment involved)

Conventional Physical Therapy: In this group, the total intervention will be for a half hour and will involve muscle elongation exercises for tight muscles of ankle and proprioceptive neuromuscular facilitation (PNF) stretching with a voluntary contraction. The therapist will strictly follow the fundamental principles of the PNF method in terms of manual contact, body position and body mechanics, verbal commands and vision. A hold-relax PNF protocol will be performed with each participant lying prone on a plinth. The therapist will resist the plantar flexion with a hold-relax PNF technique. At this moment, the participant will be asked to perform an isometric calf muscle contraction for 20 s. After the isometric muscle contraction and while maintaining the same overall position, the therapist will wait 4 s before starting the next contraction. Each participant will undergo hold-relax PNF stretching 4 times per session on the affected lower limb.

Group 3: Control group

No treatment only assessments

All participants will receive four treatment session per week for 3 weeks. At the end of the treatment, all the outcome measures will be recorded as before the intervention.

Previous interventions as of 02/04/2020:

Subjects will be randomly allocated into three groups using a block randomization method using <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. Each group needs 20 subjects so each block will have 20 subjects with 3 blocks.

Pre-testing will be done for all the primary and secondary outcome measures by an independent evaluator who is not involved with the subject's treatment.

1. Calf flexibility measured using the knee to wall test
2. Range of motion for ankle joint dorsiflexion and plantar flexion
3. Ankle proprioception
4. Dynamic balance assessed using the star excursion balance test
5. Muscle strength - ankle dorsiflexors and plantar flexors
6. Pain sensation was measured using a visual analog scale (VAS).

After the evaluation, the subjects will be provided treatment as per their group protocol.

#### Group 1: Experimental group

Physical Therapy proprioceptive neuromuscular Facilitation (PNF) + electrical stimulation device (TENS): In this group, the total intervention will be for a half hour. The therapist will strictly follow the fundamental principles of the PNF method in terms of manual contact, body position and body mechanics, verbal commands and vision. The PNF stretching protocol will be carried out as previously described (for the control group), along with (TENS) electrical stimulation using a TENS unit. Two electrodes (4 x 8 cm) will be placed 5 cm apart on the calf muscle, and 2 electrodes (5 x 5 cm) placed just distal to the popliteal fossa and the other 5 cm distal to the proximal electrode on the muscle. The electrostimulation unit will deliver a biphasic current using a symmetrical waveform at 5 Hz for 15 s. Intensity will be set to the maximum tolerated by each participant. The participants will undergo the hold-relax PNF technique along with the electrical stimulation protocol on the affected lower limb 4 times in each session.

#### Group 2: Control group 1

Conventional Physical Therapy: In this group, the total intervention will be for a half hour and will involve muscle elongation exercises for tight muscles of ankle and proprioceptive neuromuscular facilitation (PNF) stretching with a voluntary contraction. The therapist will strictly follow the fundamental principles of the PNF method in terms of manual contact, body position and body mechanics, verbal commands and vision. A hold-relax PNF protocol will be performed with each participant lying prone on a plinth. The therapist will resist the plantar flexion with a hold-relax PNF technique. At this moment, the participant will be asked to perform an isometric calf muscle contraction for 20 s. After the isometric muscle contraction and while maintaining the same overall position, the therapist will wait 4 s before starting the next contraction. Each participant will undergo hold-relax PNF stretching 4 times per session on the affected lower limb.

#### Group 3: Control group 2

No treatment only assessments

All participants will receive four treatment session per week for 3 weeks. At the end of the treatment, all the outcome measures will be recorded as before the intervention.

#### Previous interventions:

Subjects will be randomly allocated into two groups using a block randomization method using <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. Each group needs 15 subjects so each block will have 10 subjects with 3 blocks.

Pre-testing will be done for all the primary and secondary outcome measures by an independent evaluator who is not involved with the subject's treatment.

1. Calf flexibility measured using the knee to wall test
2. Range of motion for ankle joint dorsiflexion and plantar flexion
3. Ankle proprioception
4. Dynamic balance assessed using the star excursion balance test
5. Muscle strength - ankle dorsiflexors and plantar flexors
6. Pain sensation was measured using a visual analog scale (VAS).

After the evaluation, the subjects will be provided treatment as per their group protocol.

#### Group 1: Control group

Conventional Physical Therapy: In this group, the total intervention will be for a half hour and

will involve muscle elongation exercises for tight muscles of ankle and proprioceptive neuromuscular facilitation (PNF) stretching with a voluntary contraction. The therapist will strictly follow the fundamental principles of the PNF method in terms of manual contact, body position and body mechanics, verbal commands and vision. A hold-relax PNF protocol will be performed with each participant lying prone on a plinth. The therapist will resist the plantar flexion with a hold-relax PNF technique. At this moment, the participant will be asked to perform an isometric calf muscle contraction for 20 s. After the isometric muscle contraction and while maintaining the same overall position, the therapist will wait 4 s before starting the next contraction. Each participant will undergo hold-relax PNF stretching 4 times per session on the affected lower limb.

#### Group 2: Experimental group

Physical Therapy proprioceptive neuromuscular Facilitation (PNF) + electrical stimulation device (TENS): In this group, the total intervention will be for a half hour. The therapist will strictly follow the fundamental principles of the PNF method in terms of manual contact, body position and body mechanics, verbal commands and vision. The PNF stretching protocol will be carried out as previously described (for the control group), along with (TENS) electrical stimulation using a TENS unit. Two electrodes (4 x 8 cm) will be placed 5 cm apart on the calf muscle, and 2 electrodes (5 x 5 cm) placed just distal to the popliteal fossa and the other 5 cm distal to the proximal electrode on the muscle. The electrostimulation unit will deliver a biphasic current using a symmetrical waveform at 5 Hz for 15 s. Intensity will be set to the maximum tolerated by each participant. The participants will undergo the hold-relax PNF technique along with the electrical stimulation protocol on the affected lower limb 4 times in each session.

All participants will receive four treatment session per week for 3 weeks. At the end of the treatment, all the outcome measures will be recorded as before the intervention.

#### Intervention Type

Device

#### Phase

Not Applicable

#### Primary outcome(s)

1. Pain measured using a visual analogue scale (VAS) before the start of treatment and after the end of treatment
2. Range of motion of ankle dorsiflexion and plantar flexion measured using a goniometer before the start of treatment and after the end of treatment

#### Key secondary outcome(s)

1. Ankle proprioception measured using a digital dual inclinometer (Dualer IQ PRO Digital Inclinometer, J-TECH, USA) before the start of treatment and after the end of treatment
2. Dynamic balance assessed using the star excursion balance test before the start of treatment and after the end of treatment
3. Calf flexibility assessed using the knee-to-wall test before the start of treatment and after the end of treatment
4. Muscle strength assessed using a Baseline strength dynamometer (Fabrication Enterprises, USA) before the start of treatment and after the end of treatment

#### Completion date

30/04/2020

# Eligibility

## Key inclusion criteria

1. Men aged 18 to 40 years
2. Previous ankle sprain that occurred 3 months previously, diagnosed by a medical professional, e.g. orthopedics surgeon
3. Reduction in dorsiflexion of the affected ankle compared to the contralateral side

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Sex

Male

## Total final enrolment

69

## Key exclusion criteria

1. Any other general health issues
2. Lower limb pathologies e.g. pain, fracture, dislocation, grade 3 ankle sprain, bony limitation, swelling, neuropathies, and any other neuromuscular pathologies

## Date of first enrolment

05/01/2020

## Date of final enrolment

30/01/2020

# Locations

## Countries of recruitment

Saudi Arabia

## Study participating centre

King Khalid University, Medical City

Guraiger

Abha

Saudi Arabia

3665

## Sponsor information

### Organisation

King Khalid University

## Funder(s)

### Funder type

Other

### Funder Name

Investigator-funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available if required by the journal

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		23/09/2020	17/05/2022	Yes	No