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

Submission date
28/11/2019

Recruitment status
No longer recruiting

Registration date
14/12/2019

Overall study status
Completed

Last Edited
17/05/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Participant information sheet not available in web format, please use contact details to request a participant information sheet.

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 measure
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

Secondary outcome measures
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

Overall study start date
24/08/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
60

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

Sponsor details
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Sponsor type
University/education

Website
https://www.kku.edu.sa/en/

Funder(s)

Funder type
Other

Funder Name
Investigator-funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/12/2020

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?
Results article		23/09/2020	17/05/2022	Yes	No