

# Shockwave therapy and exercise for plantar heel pain: A pilot study

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<b>Registration date</b> 31/07/2019	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/09/2021	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Musculoskeletal disorders are having an increasing burden on society with costs to healthcare systems and individuals. Chronic heel pain known as plantar fasciopathy is a common musculoskeletal disorder of the foot, resulting in chronic pain and impaired function. Extracorporeal shockwave therapy (ESWT) involves using mechanical shockwaves applied from an electrical device outside the body to stimulate healing in chronic musculoskeletal disorders. In clinical practice, ESWT is often used in combination with exercise, although this has been poorly addressed in previous studies. Specific strengthening and stretching exercises and ESWT alone for plantar fasciopathy been found to be effective treatment interventions in randomised controlled trials (RCTs). However there have been no studies comparing these two interventions against each other and a combined intervention. A three-arm RCT comparing these three groups would be the ideal way to determine the most effective treatment protocol for plantar fasciopathy. There have also been no qualitative studies investigating patients' perceptions, expectations and acceptability of these interventions. Therefore, the proposed mixed methods study will involve a pilot RCT and qualitative semi-structured interviews. The pilot RCT will test the trial procedures and process evaluation of a larger-scale RCT, which would be adequately powered to determine effectiveness of the three interventions, allowing for recommendations. The qualitative semi-structured interviews will allow investigation of patients' perceptions, expectations and acceptability of these interventions. Not only would this data help explain the intervention outcomes it would help in determining if these interventions are acceptable to patients in clinical practice.

### Who can participate?

Participants aged over 18 with diagnosed plantar fasciopathy lasting 3 months or longer, who have no contraindications to receiving the interventions.

### What does the study involve?

Participants will be recruited from NHS Grampian podiatry, Robert Gordon University and the general population based on pre-determined criteria. Interested participants will attend an initial screening session and baseline outcome measures and demographic information will be collected. Consenting participants will be randomly allocated to one of three treatment groups: shockwave therapy, physiotherapy exercise, and a combined group. Participants would then

come to Robert Gordon University (RGU) physiotherapy clinic on three occasions, to receive treatment. All participants are then followed up at 1 month, 3 months and 6 months after treatment, when their level of pain, foot function and general quality of life are assessed. Selected participants will also be invited to undertake telephone semi-structured interviews following trial completion.

What are the possible benefits and risks of participating?

There are no additional risks to participating in the study compared to usual physiotherapy. The main potential risk is temporarily increased pain following treatment. The treatment interventions have been previously studied in RCTs and have been found to be effective for pain and function for plantar fasciopathy.

Where is the study run from?

The Robert Gordon University (RGU), Aberdeen, Scotland, United Kingdom

When is the study starting and how long is it expected to run for?

January 2019 to June 2020 - 18 months

Who is funding the study?

Robert Gordon University

Who is the main contact?

Professor Kay Cooper

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Kay Cooper

### ORCID ID

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

SSH/19/19

## **Study information**

### **Scientific Title**

Comparison of Radial Extracorporeal shockwave therapy, physiotherapy, and a combined intervention for plantar fasciopathy: a mixed methods pilot RCT.

### **Study objectives**

The combination of radial shockwave therapy and physiotherapist-delivered specific plantar fascia exercises is more effective than either intervention alone for pain and function in plantar fasciopathy at 1 and 3-month follow-up.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Approved 04/06/2019, School of Health Sciences REC (Faculty of Health and Social Care, Robert Gordon University, Garthdee Road, Aberdeen, AB10 7QG; 01224 263250; j.johnston4@rgu.ac.uk), ref: SHS/19/19.
2. Approval from NHS HRA REC to follow.

### **Study design**

Mixed methods pilot randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Pilot Randomised controlled trial (RCT)

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **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**

Plantar fasciopathy

## **Interventions**

Group I: Radial Shockwave therapy following standardized protocol (EMS Swiss DolorClast), performed 3x in weekly intervals (Week 1, 2 and 3) combined with Plantar fascia-specific strengthening and stretching instruction on Weeks 1 and 3. These exercises are continued and progressed at home for 12 weeks. This group will receive a telephone call from the researcher at week 5 to ensure exercise progression. Patients will receive standardized written plantar fasciopathy education and advice.

Group II: Plantar fascia-specific strengthening and stretching x3 instruction sessions (Week 1, 3 and 5) and performed over 12 weeks at home. Patients will receive standardized written plantar fasciopathy education and advice.

Group III: Radial Shockwave therapy following standardized protocol (EMS Swiss DolorClast), performed 3x in weekly intervals (Week 1, 2 and 3). Patients will receive standardized written plantar fasciopathy education and advice.

Purposely selected participants will undergo semi-structured interviews following intervention completion to collect qualitative process evaluation data.

Follow-up and secondary outcome measure completion: at 1 month, 3 months, and 6 months from baseline.

Consenting participants with diagnosed PF who meet inclusion and exclusion criteria will be randomised to one of three groups. An independent assessor will inform participants of group allocation after conducting randomisation using a web-based randomisation service with random variable block-size, with secure password and protected login.

## **Intervention Type**

Other

## **Primary outcome measure**

This is a pilot study. Primary outcome will be the efficacy of the study procedure, including participant recruitment, retention, intervention acceptability, trial procedures and process evaluation. Acceptability will be measured by patient interview.

## **Secondary outcome measures**

1. Change of the sum score of the Revised Foot function Index (FFI-R) from baseline to month one, month three and month six.
2. Change of the sum score of Foot and Ankle Ability Measure (FAAM) from baseline to month one, month three and month six.
3. Change of 100mm VAS pain scale from baseline to month one, month three and month six.
4. Change of Roles and Maudsley Score from baseline to month one, month three and month six.
5. Change of EQ-5D-5L Quality of life score from baseline to month one, month three and month six.
6. Global rating of change (GROC) score from baseline to month one, month three and month six.

## **Overall study start date**

28/01/2019

## **Completion date**

01/06/2020

## **Reason abandoned (if study stopped)**

Changes in personnel and funding

# Eligibility

## Key inclusion criteria

1. Adults over the age of 18
2. Diagnosis of plantar fasciopathy by referring clinician to include:
  - 2.1 Heel Pain in the morning or after sitting for extended periods
  - 2.2 Localised pain on palpation where the plantar fascia attaches to the heel – medial calcaneal tuberosity
  - 2.3 Increased pain with walking or standing for extended periods
3. History of at least 3 months of heel pain prior to beginning trial
4. Willingness to abstain from any other treatments during the trial
5. Signed informed consent form

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

48

## Key exclusion criteria

1. Neurological abnormalities, peripheral neuropathy or nerve entrapment syndromes (e.g., tarsal tunnel syndrome)
2. Infections or tumours of the lower extremity, active malignancy
3. Vascular abnormality (e.g., severe varicosities, ischaemia)
4. Arthrosis or arthritis of the foot, rheumatoid arthritis
5. Systemic inflammatory disease, osteomyelitis
6. Dysfunction of the foot or ankle (e.g. chronic instability)
7. Corticosteroid injection or shockwave therapy within 6 weeks of beginning trial interventions
8. Calcaneal stress fracture, plantar fascia rupture or previous surgery for heel spur or plantar fascia
9. Bleeding disorder or haemophilia or active coagulation therapy
10. Cardiac pacemaker
11. Pregnancy

## Date of first enrolment

01/04/2019

## Date of final enrolment

31/12/2020

# Locations

## Countries of recruitment

Scotland

United Kingdom

## Study participating centre

**Robert Gordon University**

School of Health Sciences

Garthdee Road

Aberdeen

United Kingdom

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# Sponsor information

## Organisation

Robert Gordon University

## Sponsor details

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j.johnston@rgu.ac.uk

## Sponsor type

University/education

## Website

<https://www.rgu.ac.uk/research/research-projects/about-our-research>

## ROR

<https://ror.org/04f0qj703>

# Funder(s)

## Funder type

University/education

**Funder Name**

Robert Gordon University

**Alternative Name(s)**

RGU

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Summary findings will be sent to all participants; presentations to local physiotherapists and other interested groups; presentation at UK physiotherapy conference.  
Publication in high-impact physiotherapy-related journal.

**Intention to publish date**

01/01/2021

**Individual participant data (IPD) sharing plan**

The current data sharing plans for this study are unknown and will be available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date