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

Submission date
19/03/2019

Recruitment status
Stopped

Registration date
31/07/2019

Overall study status
Stopped

Last Edited
22/09/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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.
Purposively 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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Scotland

Study participating centre
Robert Gordon University
School of Heath Sciences
Garthdee Road
Aberdeen
United Kingdom
AB10 7QG

Sponsor information

Organisation
Robert Gordon University

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes