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Do stretching exercises reduce plantar pressure in the at-risk diabetic foot?

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
03/01/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0203121474

Study information

Scientific Title
-

Study objectives

As limited joint movement does not affect the joints directly but rather the soft tissues surrounding them, we hypothesise that mobilisation techniques may prevent some of the destructive, pathomechanical forces initiated by joint limitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Diabetes

Interventions
A pilot pragmatic, randomised control trial will be undertaken to assess the effect of teaching stretching exercises to patients with limited joint movement. The primary outcomes will be the improvement in the range of movement and a reduction in the peak plantar pressure.

Measurement of range of movement and plantar pressure will be taken monthly; 50% of recruits will be required to follow a set exercise programme twice weekly, for a total of 12 weeks.

Patients will be contacted fortnightly to monitor progress.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
This is a pilot study that aims to provide preliminary data to test the hypothesis that regular stretching exercises of the foot and ankle will reduce the risk of ulceration in diabetic, neuropathic feet by improving the range of movement of the ankle and hence lower peak plantar pressures. We will evaluate using a randomised control study of a home treatment plan where diabetic patients with neuropathy and limited joint mobility are taught to use regular stretching exercises.

Study endpoints: To assess if this treatment (compared to no treatment):
1. Increases the range of movement at the ankle joint
2. Reduces peak plantar pressure

Key secondary outcome(s)

Not provided at time of registration

Completion date
31/10/2003

Eligibility

Key inclusion criteria
1. Diabetic subjects attending the Diabetes and Vascular Centre and local chiropody clinics will be considered for the trial
2. Over 35 years of age
3. Diabetes mellitus
4. Peripheral sensory neuropathy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Arthritic conditions (e.g., osteo/rheumatoid)
2. Partial amputation
3. Previous severe trauma (fracture/tendon rupture/charcots)
4. Excessive scar tissue
5. Surgical intervention
6. Severe gait disturbance
7. Peripheral vascular disease (PVD)
8. Known collagen disorders

Date of first enrolment
27/01/2003

Date of final enrolment
31/10/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter
United Kingdom
EX2 5BW

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Royal Devon and Exeter NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration