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Feasibility study to evaluate the clinical and cost effectiveness of foot orthoses in the management of plantar heel pain

Submission date
18/12/2002

Recruitment status
No longer recruiting

Registration date
18/12/2002

Overall study status
Completed

Last Edited
09/10/2007

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Keith Rome

Contact details
University of Teesside
School of Health and Social Care
Middlesbrough
United Kingdom
TS1 3BA
+44 (0)1642 384977
K.Rome@tees.ac.uk

Additional identifiers

Protocol serial number
RRC300/SG

Study information

Scientific Title

Study objectives
Not provided at time of registration

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
Plantar heel pain

Interventions
Two types of foot orthoses (based on costs and function) were measured at baseline, 4 and 8 weeks using general (EQ5D), specific (Foot Health Status Questionnaire) outcome measures together with an economic questionnaire

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/01/2002

Eligibility

Key inclusion criteria
48 patients clinically diagnosed with plantar heel pain. The inclusion criteria included the following:
1. Unilateral plantar heel pain of at least 2-months duration
2. A history of night-time or early morning pain, which decreases after walking, and/or increases after exercise or prolonged periods of standing
3. Heel pain severe enough to either cause a reduction in physical activity, a visit to a health

professional, or the use of medication
4. Good general health

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2001

Date of final enrolment
01/01/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Teesside
Middlesbrough
United Kingdom
TS1 3BA

Sponsor information

Organisation
North Tyneside AHA Trust Research Unit (UK)

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - Directorate of Health & Social Care

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/05/2004		Yes	No