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Pilot studies of the effects of custom semi-rigid full-foot orthotics on planta-surface foot pain and anterior knee pain: towards evidence-based practice

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 21/11/2019	**Condition category** Signs and Symptoms	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0544093555

Study information

Scientific Title
Pilot studies of the effects of custom semi-rigid full-foot orthotics on planta-surface foot pain and anterior knee pain: towards evidence-based practice

Study objectives
Orthotics treatment of foot and knee pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: knee/foot pain

Interventions
Subjects will be referred via specialist orthopaedic and rheumatology clinics and will sign informed consent. They will be assessed by a Chartered Physiotherapist (Kristin Giussani) which will include measurements of strength, range of movement, and outcome measures of pain and function. They will then be fitted with either a real or placebo customised shoe insert (an orthotic) which they will use for a 1-month period. The patient will keep a diary of their pain and function over a 1-month period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
31/10/2000

Completion date
21/10/2003

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40 subjects (PROJ 10/10/2000)

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/10/2000

Date of final enrolment
21/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Box 194
Cambridge

United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration