ISRCTN43076496 https://doi.org/10.1186/ISRCTN43076496

A 3D printed knee brace to improve symptoms, biomechanics and daily life among medial knee osteoarthritis patients

Submission date
27/07/2016

Recruitment status
No longer recruiting

Registration date
16/08/2016

Overall study status
Completed

Last Edited
20/05/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis is the 'wear and tear' form of arthritis affecting the joints. Around 250 million people in the world (3.8%) have knee osteoarthritis. Due to aging and increasing obesity, the prevalence of knee osteoarthritis is expected to increase in developed countries in the next 20 years. Knee osteoarthritis decreases patients' quality of life through chronic pain, joint stiffness, and reduced social activity, which influence emotional wellness as well. Knee osteoarthritis can also lead to or increase misalignment of the thighbone and shinbone and increase the force on the knee joint, leading patients into a vicious circle by increasing knee pain, decreasing activities, increasing weight and progressing the disease. A knee brace is a brace worn to strengthen the knee and is a recommended treatment for knee osteoarthritis. It aims to reduce misalignment of the limb. However, the main issue is patients' poor compliance to the treatment because of lack of effectiveness, more drawbacks than benefits, discomfort, bad fitting, movement of the brace, bulkiness, appearance, skin irritation, blisters and too much pressure on the knee. By its freedom in design, 3D printing may resolve most of these complaints. This study aims to compare the effectiveness and comfort of a knee brace made by 3D printing and a conventional knee brace.

Who can participate?
Patients aged 40 to 70 with medial knee osteoarthritis

What does the study involve?
Participants are in the study for 10 weeks. During this period, they wear two different knee braces for two weeks each with a 1-week period without a knee brace in between. Participants attend Glasgow Caledonian University for five visits: once for leg measurement to make the knee braces and four times to fill in questionnaires and perform gait (walking) analysis. Participants also wear activity monitors for three non-consecutive weeks.

What are the possible benefits and risks of participating?
By participating in this study, participants may benefit from pain relief, symptom reduction and

improvement in daily life activities. Besides, participants keep the knee brace of their choice at the end of the study. Wearing knee braces may sometimes lead to a rash, allergic skin irritations, and knee lock. However, these risks are minors and reversible.

Where is the study run from?
The Institute for Applied Health Research of Glasgow Caledonian University (UK)

When is the study starting and how long is it expected to run for?
January 2017 to June 2017

Who is funding the study?
EU Seventh Framework Programme

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02873403

Protocol serial number
AMKNEEBRACE01

Study information

Scientific Title

A novel additive manufacturing knee brace to improve symptoms, biomechanics and daily life in medial knee osteoarthritis: a crossover randomized controlled trial

Study objectives
The new knee brace has at least equivalent clinical and biomechanical effectiveness and better comfort and compliance for patients than a conventional customized knee brace for management of the knee osteoarthritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS and Glasgow Caledonian University research ethics committee - approval pending

Primary study design
Interventional

Study design
Double-blinded crossover superiority randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Medial tibiofemoral knee osteoarthritis

Interventions
Participants will be in the study for 10 weeks. During this period, they will wear two different knee braces (Unloader One knee brace and novel knee brace) and for two weeks each with a 1-week period without knee brace between. Participants will have five visits to Glasgow Caledonian University: once for leg measurement to make the knee braces and four times to fill questionnaires and perform gait analysis. Besides, they will wear activity monitor for 3 non-consecutive weeks.

Intervention Type
Device

Primary outcome(s)
1. Knee pain before and after each 2-week intervention, measured with 10-cm visual analog scale after each condition of laboratory assessment
2. Knee adduction moment before and after each 2-week intervention - peaks and angular impulse from motion capture system

Key secondary outcome(s)
1. Knee brace comfort before and after each 2-week intervention, measured with 10-cm visual analog scale after each condition of laboratory assessment
2. Stability feelings before and after each 2-week intervention, measured with 10-cm visual analog scale after each condition of laboratory assessment
3. Symptoms and quality of life before and after each 2-week intervention, measured with KOOS and MOS SF-36 questionnaires subscales

4. Amount of daily physical activities during the second week of each intervention period - four components of physical activity considered by the World Health Organization (WHO) - Frequency, Intensity, Time and Type (FITT) - measured with an activity monitor. We are particularly interested in daily activities and intensities
5. Knee flexion moment before and after each 2-week intervention - peak from motion capture system
6. Lower limb symmetry before and after each 2-week intervention - duration of phases in seconds and percentage, step width and length measured by gait analysis
7. Knee range of motion before and after each 2-week intervention - knee flexion/extension, adduction/abduction, internal/external rotation angles measured by gait analysis

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Male or female aged between 40 and 70 years old having radiological and symptomatic medial knee osteoarthritis (Kellgren-Lawrence grade II, III or IV) according to the American College of Rheumatology's clinical and radiological criteria (Altman, 1986)
2. Average knee pain > 4/10 (VAS score assessed three times in two weeks before being included)
3. Not currently wearing knee brace
4. Varus knee alignment equal or superior to 2°
5. No or light pain from the hips, ankles, feet or lumbar spine
6. Moderately physically active
7. Able to understand written and spoken English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Mild knee osteoarthritis (Kellgren-Lawrence grade I)
2. Lateral or patellar knee osteoarthritis
3. Chronic diseases or conditions (e.g., diabetes, osteoporosis, heart disease, hypertension, neurological disorders)
4. Stroke history
5. Inflammatory arthritis (gout, rheumatoid arthritis, psoriatic arthritis etc)
6. Musculoskeletal disorders that could influence their ability to stand and walk
7. Morbid obesity (BMI > 35)
8. Intra-articular corticosteroid/hyaluronan injection in the affected knee in the past 3 months
9. Unstable medication schedule and medication that causes dizziness

10. Severe recent modification of diet
11. Prosthetic implants in the hip, knee or ankle joint
12. Poor skin condition
13. Unable to walk, walk up and down stairs or any condition contraindicating the demands of the gait analysis

Date of first enrolment
01/02/2017

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Glasgow Caledonian University
Glasgow
United Kingdom
G4 0BA

Sponsor information

Organisation
Peacocks Medical Group Ltd (UK)

ROR
https://ror.org/02hg69287

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)

EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because of the project’s commercial nature. The data will be held at Peacocks Medical Group main office.

IPD sharing plan summary
Not expected to be made available