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Effect of exercises combined with education and self-management skills on patients with knee osteoarthritis (OA)

Submission date
17/06/2013

Recruitment status
No longer recruiting

Registration date
22/07/2013

Overall study status
Completed

Last Edited
27/11/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
When we stand, walk or climb stairs our weight is passed on through our knee joint. The way this weight is transmitted and its measurement is defined as load. The amount of load on the knee joint in knee osteoarthritis (weakening of the knee joint) is increased, which results in deterioration of the condition. Treatments aiming to decrease the load on the knee joints are needed. Therefore, we have developed an exercise programme based on the available evidence. We now wish to find out whether it decreases the load on the knee and/or decreases pain, and improves strength and function. We aim to gain a more thorough understanding of the loading on the knee joint that causes osteoarthritis and the effect of a well-established 6-week exercise programme on this load.

Who can participate?
Participants diagnosed with knee osteoarthritis can participate in the study.

What does the study involve?
We will ask you to attend two testing sessions, before and after you attend the exercise programme. We will also ask you to attend the exercise programme in the church hall in The Avenue Methodist Church in Sale. We will arrange an appointment with you for the first testing session at The University of Salfords Gait Laboratory. Here we will explain the study in full. We will ask you to complete a consent form after answering any questions you may still have. We will then ask you to complete three questionnaires about the way osteoarthritis has affected your everyday life, and measure your weight, balance, walking pattern and strength of your knee and hip muscles.
This will take about 2.5 hours to complete. The same procedure will be repeated in the second testing session after you have finished the exercise programme. The testing session will include a break for refreshments and for you to have a short rest. After this, we will arrange a date with you to start the class exercise programme. This will last 6 weeks and is held in the church hall in The Avenue Methodist Church in Sale. You will be asked to come once a week for one hour of exercises and a 10-15 minute arthritis education session (i.e. 1¼ hours in total). The programme will be delivered by the researcher (who is a registered physiotherapist), a member of the

physiotherapy staff at Trafford General Hospital and a physiotherapy assistant. You will be asked to do the exercises everyday at home for 10-15 minutes. After each exercise session there will be a short arthritis education meeting. We will discuss information about knee osteoarthritis and practical advice about how to manage any effects of your arthritis (e.g. pain and any difficulties with everyday activities).

What are the possible benefits and risks of participating?
The exercises have found to decrease pain and improve function and strength. There are no risks in performing the assessment procedures as this is a routine measurement of your usual everyday activities. The exercises are designed to begin at the level of your ability and muscle strength, which limits the possibility of injuring your muscles or stressing your knee joint. After the first session of the exercise programme, you might experience some muscle soreness. This is normal because to increase the strength of your muscles they need to be loaded while they move, and as the muscles are not used to this load you will experience some discomfort.

Where is the study run from?
The study is run from the University of Salford, UK and The Avenue Methodist Church, Sale, UK.

When is the study starting and how long is it expected to run for?
The study started in April 2011 and ended in May 2012.

Who is funding the study?
This study is funded by The University of Salford, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The effect of Combining knee and hip Exercises on the Load in Knee OsteoArthritis: a pilot study (CELKOA)

Acronym
CELKOA

Study objectives
Hypothesis 1: Strengthening the hip and knee muscles will decrease the loading on the medial compartment and decrease the external knee adduction moment (EKAM).
Hypothesis 2: An exercise programme combining concentric, eccentric and isometric contractions will decrease the co-contraction of the muscles around the knee and this will reduce the load.
Hypothesis 3: Exercises will decrease pain and improve function by improving strength, self-efficacy, decreasing load, muscle activity and changing the co-contraction of the muscles around the knee joint.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was obtained from the North West Research Ethics Committee 8 Greater Manchester East (Reference number 11/NW/0051) on 04/03/2011, Research and Development department at Trafford General Hospital and University of Salford Research and Governance Ethics Committee.

Study design
One group pre-post pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Knee osteoarthritis (degeneration of the knee joint)

Interventions
Participants attended a six-week group exercise programme once a week in the church hall at The Avenue Methodist Church in Sale. It was delivered by the investigator, a physiotherapist, and a physiotherapy assistant from Trafford General Hospital. Each session included a 20 minutes education session followed by an hour of exercises. The pilot exercise programme consisted of strength and balance exercises combined with education.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
External knee adduction moment (EKAM): the EKAM was assessed during gait. It was also assessed in single leg stance (SLS). This is referred to as single leg stance knee adduction moment (SSKAM). Additionally, knee adduction angular impulse (KAAI) during gait was assessed.

Key secondary outcome(s))
1. Hip, knee, and ankle kinematics and kinetics in the coronal and sagittal planes and temporo-spatial parameters: some of these measures include: speed, stance time, step length, and the external hip adduction moment.
2. Muscle strength: all isokinetic and isometric testing were performed using the Biodex system 3 isokinetic dynamometer (Biodex Medical Systems, Shirley, N.Y., USA). The strength of the knee flexors and extensors was assessed concentrically at 60°/s and isometrically at 45°. The hip abductors were assessed isometrically at 0°.
3. Dynamic balance: a modified Star Excursion Balance Test (SEBT) was used to assess dynamic balance.
4. Muscle co-contraction: surface electromyography (EMG) data were collected using a Noraxon Telemyo system (www.noraxon.com) at a sampling rate of 3000Hz. Eight channels were used to record average activation with electrodes placed on the right and left vastus lateralis (VL), vastus medialis (VM), biceps femoris (BF), and semitendinosus (ST) muscles.
5. Knee injury and Osteoarthritis Outcome Score (KOOS)
f6. Arthritis self-efficacy questionnaire
7. Medical Outcomes Study 12-item Short-Form Health Survey (SF-12v2)
8. Adherence

Completion date
10/05/2012

Eligibility

Key inclusion criteria
1. Participants diagnosed with medial knee OA either clinically or radiographically by a consultant /GP and meeting the American College of Rheumatology (ACR) criteria for knee OA (Altman, 1987)
2. 40 years or older
3. Able to walk for at least 100 metres.
4. Speak and understand English as the patients needed to understand the patient information sheet and the consent forms, which were written in English. The educational materials and patient reported measures were also in English. As a pilot study, there was not sufficient funding to translate these into other languages.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Total final enrolment
19

Key exclusion criteria
1. Diagnosis of patellofemoral or lateral knee OA more than medial
2. Currently wearing a brace or insoles
3. Currently using cane or other assistive devices to help mobility
4. Severe cognitive, cardio-respiratory, musculoskeletal or neurological problems other than knee OA
5. Taking medications that would limit participation in the exercise programme and/or assessments
6. A history of high tibial osteotomy or other realignment surgery or total knee replacement. The effect of a conservative intervention (i.e. exercises) on loading is under investigation and these interventions change the loading on the knee and are considered the last choice of treatment with knee OA.
7. Corticosteroid injection in the knee in the last three months to ensure it does not interfere with the results of the exercise programme, as it has short-term effect on pain (Bellamy et al., 2006)
8. Current participation in other treatment programmes that might affect the results of this pilot study, such as other exercise programmes, manual therapy, or acupuncture
9. Gross ligament instability

Date of first enrolment
25/04/2011

Date of final enrolment
10/05/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Room PO18, Brain Blatchford Building
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Sponsor information

Organisation
University of Salford (UK)

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
University/education

Funder Name
University of Salford (UK)

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	01/01/2016	27/11/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes