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Reducing knee load by changing the walking pattern in patients with knee osteoarthritis

Submission date
11/08/2017

Recruitment status
No longer recruiting

Registration date
14/08/2017

Overall study status
Completed

Last Edited
28/08/2018

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis is a condition that causes joints to become painful and stiff. Real-time feedback based on the walking (gait) pattern, particularly the movement of the knee and the feet, is effective for gait retraining in patients with osteoarthritis of the knee (KOA). Changing the gait pattern reduces the loads on the medial compartment (inside) of the knee. The aim of this study is to provide proof-of-concept for the use of real-time feedback in gait retraining to decrease the load on the knee in patients with knee osteoarthritis.

Who can participate?
Patients aged between 50 and 75 with knee osteoarthritis

What does the study involve?
Participants are trained for a period of 6 weeks to walk with a modified gait pattern. This training is carried out once a week for about one hour at the Virtual Reality lab in the VU medical center. Motion capture equipment is used to track the movement of the legs and trunk during walking. Participants walk on a treadmill and are provided with feedback on a screen with a virtual reality environment in front of the treadmill while they are walking. The feedback is based on the position of the foot and participants are encouraged to changed this in order to reduce the forces in the knee. Follow-up measurements are carried out 3 and 6 months after the end of the training. As well measuring changes in the knee forces, changes in knee pain and function are also measured using questionnaires.

What are the possible benefits and risks of participating?
Participants may benefit from reduced pain during the training program and damage to the knee joint (progression of the disease) may be reduced over a longer period of time. The total risk of side effects from the training or from walking on a treadmill is very small. Participants wear a safety harness while walking on the treadmill in case of trips or falls.

Where is the study run from?
VU Medisch Centrum (Netherlands)

When is the study starting and how long is it expected to run for?
July 2015 to May 2017

Who is funding the study?
European Union Marie Curie Actions (EU)

Who is the main contact?
Miss Rosie Richards

Contact information

Type(s)
Public

Contact name
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Protocol serial number
NL51889.029.15

Study information

Scientific Title
The effect of gait re-training using real-time feedback on the knee joint moments in patients with medial knee osteoarthritis

Study objectives
Previous studies have shown that with modifications to the gait (walking) pattern, such as walking with a modified foot progression angle or wider steps, can reduce the knee joint loading. This is important in patients with medial knee osteoarthritis where the knee loading is often higher and is associated with faster progression of knee osteoarthritis. By walking with small modifications the loading can be reduced.

The principal hypothesis is that the knee adduction moment, which is a representative measure of knee joint load, will decrease as a result of a six week gait retraining program using real-time feedback to train people with knee osteoarthritis to walk in a modified gait pattern.

Ethics approval required
Old ethics approval format

Ethics approval(s)
De Medische Ethische Toetsingcommissie VU Medisch Centrum (The Medical Ethics Review Committee of the VU medical centre), 02/09/2016, ref: 2015.281

Primary study design
Interventional

Study design
Interventional single treatment arm

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Gait training is delivered through use of motion capture technology with real-time feedback to train people to walk with increased toe-in gait, (toes pointing straight forwards or slightly inwards). The position of the feet is measured in real-time using the motion capture system and the angle is projected onto a large screen in front of the patient. The patient then uses the feedback to adjust the position of their feet relative to the target angle. Training is provided for approximately 30 minutes per week over a period of 6 weeks.

Training is provided by the researcher (PhD student) and a research assistant. The researcher has expertise in gait analysis and use of real-time feedback. The background of the researcher is in gait and movement analysis in primarily children with cerebral palsy, but also in adults with orthopaedic pathologies. Further they have a Bachelor's degree in Medical Engineering and a Master's Degree in Medical Physics and Engineering. The research assistant has a background in Human Movement Sciences, with a Bachelors and Research Masters in this area. Consultation with an experienced physiotherapist (with many years of experience in treatment and research in patients with knee osteoarthritis) was also available throughout the study.

Training was provided via face-to-face delivery and each patient attended for individual sessions, since the training was personalised to the individual. Training was provided at the Virtual Reality Laboratory at the VU University medical center in Amsterdam. The Virtual Reality Laboratory includes a GRAIL system (https://www.motekforcelink.com/product/grail/) which incorporates a treadmill with 2 force plates, motion capture equipment and a large screen onto which a virtual reality environment can be projected. Images and more details (in Dutch) of the Virtual Reality lab can be found here https://www.vumc.nl/afdelingen/revalidatiegeneeskunde /klinischebewegingsanalyse/VRL.pdf/

Training is provided once per week for 6 weeks hence 6 times in 6 weeks, scheduled at the same time each week where possible. Each session lasted approximately one hour, of which approximately 30 minutes was training and the rest of the session was for preparing the patient and other necessary activities. Duration of the training increased weekly.

The training was tailored to the individual by setting the target for foot progression angle on an individual basis based on results from several previous studies which showed that personalisation of gait training is necessary for optimal results. Patients attended for one session prior to the start of the training process in order to determine the optimal training plan per individual.

To measure the forces and the movement of the knee, motion capture equipment is used (gait real-time analysis interactive lab including an instrumented treadmill, a motion capture system), allowing the movement of the legs and trunk to be tracked during walking. Patients will walk on a treadmill and will be provided with feedback on a semi-cylindrical screen with virtual reality environment in in front of the treadmill while they are walking. The feedback will be based on the position of the foot and patients will be encouraged to modify this in order to reduce the forces in the knee. Follow-up measurements will be carried out 3 and 6 months after the end of the training to assess changes in the knee forces and movement. As well measuring changes in the knee forces, we also want to measure changes in knee pain and function using standardised questionnaires.

Intervention Type
Other

Primary outcome(s)
The first peak of the knee adduction moment. This is generally accepted to be a representation of the knee joint loading in the medial compartment of the knee and is an important measure in patients with medial knee osteoarthritis. It is calculated from the measurement of the knee joint position using motion capture equipment and the ground reaction forces using two force plates. In this study a comparison of the first peak of the knee adduction moment is made at baseline, end of training programme (week six) and three and six month follow up (3 and six months after the last training session).

Key secondary outcome(s)
1. Pain, functional ability and knee joint stiffness is measured using the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index, https://www.rheumatology.org/I-Am-A/Rheumatologist/Research/Clinician-Researchers/Western-Ontario-McMaster-Universities-Osteoarthritis-Index-WOMAC) questionnaire at baseline, end of training programme (week six) and 3 and 6 month follow up (3 and 6 months after the last training session)
2. Self-reported pain is measured using a NRS (numeric rating scale) at baseline, end of training programme (week six) and 3 and 6 month follow up (3 and 6 months after the last training session)

Completion date
30/05/2017

Eligibility

Key inclusion criteria
1. Knee osteoarthritis on the medial compartment based on the ACR criteria
2. Age between 50 and 75 years
3. BMI between 20 and 30kg/m^2
4. Maximum score of 7 on the numeric rating scale (NRS) for pain intensity during the past two

weeks
5. Ability to walk independently and unaided (without use of a walking frame, crutches or other assistive device) for 30 minutes

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Total knee replacement patients (patients who have already undergone surgery or patients who are planned for surgery)
2. Rheumatoid arthritis or other form of inflammatory arthritis such as crystal arthropathy or septic arthritis
3. Hip osteoarthritis
4. Participants in other experimental research studies (including but not limited to the Vitamin D study and the COOA study)
5. Poor eyesight which could restrict the ability ro understand and use the real-time visual feedback

Date of first enrolment
03/12/2015

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
VUmc
De Boelelaan 1117, 1081 HV Amsterdam
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Sponsor information

Organisation
VU Medisch Centrum

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Government

Funder Name
European Union Marie Curie Actions- Initial Training Networks FP7 (607510)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available because the trialists do not have approval from their local ethics committee for data sharing. However, it is possible that this will change in the future.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2018		Yes	No
Basic results		28/08/2018	28/08/2018	No	No
Protocol file	version v5	18/05/2016		No	No