Gait retraining by real-time feedback in patients with knee osteoarthritis (KneeMo Feedback Study)

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A) To evaluate the use of real-time visual and audio feedback on the knee adduction moment and on kinematic patterns during gait in patients with knee osteoarthritis to decrease the biomechanical load on the knee via implicit learning and explicit...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON43704

Source
ToetsingOnline

Brief title
KneeMo Feedback Study

Condition

- Joint disorders

Synonym
osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: feedback, gait, knee, osteoarthritis

Outcome measures

Primary outcome

Primary outcome measures are change in external knee adduction moment (KAM) between different conditions. KAM will be measured during the various gait modification conditions (study A: 1. baseline; 2. KAM feedback without kinematic instructions, audio and visual feedback; 3. Kinematic feedback without further instructions (toe-out or -in, step width and medial thrust); 4. KAM feedback with additional verbal kinematic instructions about an effective gait pattern that can be sustained in daily life: 5. maintaining the pattern from 4. without any feedback) and during and after the training sessions (study B: 1. baseline; 2. try to replicate the pattern learned in study A without feedback; 3. KAM feedback with kinematic instructions from study A; 4. maintaining the pattern from 3. without feedback; follow-up after 3 and 6 months). Linear mixed models will be used to calculate statistical differences. Pain as measured by the numeric rating scale and WOMAC questionnaire will also be a primary outcome.

Secondary outcome

Secondary parameters will include external knee flexion moment (KFM), and kinematic pattern (joint angles and temporal-spatial parameters) as measured by the GRAIL; these will be assessed during the different gait modification patterns (as for the KAM). EMG cocontraction is also a secondary outcome.

Study description

Background summary

Real-time visual and audio feedback of the gait pattern is assumed to be effective for gait retraining in patients with osteoarthritis of the knee (KOA). Modification of the gait pattern results in a change in knee joint loading. The external knee adduction moment (KAM) is considered to be a good surrogate measure of internal loading on the medial side of the tibiofemoral condyles. KOA patients with medial compartment OA often show a higher KAM compared to healthy subjects. In healthy subjects it has been shown that direct real-time visual feedback of the KAM was effective in reducing the knee joint loading. A gait training protocol with direct KAM feedback in which patients can develop preferred individual kinematic strategies needs to be developed.

Study objective

A) To evaluate the use of real-time visual and audio feedback on the knee adduction moment and on kinematic patterns during gait in patients with knee osteoarthritis to decrease the biomechanical load on the knee via implicit learning and explicit instructions; (B) To provide proof-of-concept for the use of real-time feedback as a clinical intervention on gait retraining to decrease the biomechanical load on the knee in patients with (medial compartment) knee osteoarthritis during a 6 weeks training and 3 and 6 months follow-up.

Study design

Cross-sectional observational study (A) and uncontrolled trial (B). In the first study (A) a biofeedback algorithm using computer modelling will be tested on its feasibility in a cross-sectional observational study to establish measurement capability and quality in patient with OA of the knee (n=41). In a second study (B) a small-scale exploratory intervention (uncontrolled trial) will be carried out during 6 weeks to provide evidence for real-time feedback as an intervention in modifying gait in a sub-sample of the previous study 30. Follow-up measurements will be carried out 3 and 6 months after the end of the training. Modification of knee load and gait characteristics will be assessed by 3D motion analysis on the GRAIL (Gait real-time analysis interactive lab including an instrumented treadmill, a motion capture system and a semi cylindrical screen with virtual reality environment and real-time gait feedback).

Intervention

Training protocol for gait modification once every week during 6 weeks, including feedback on the external knee adduction moment (KAM) and advice on

home training.

Study burden and risks

Potential participants of the study are registered as members of the AMS-OA cohort (Reade) and selected patients from our own database (via the newsletter and local newpapers) will be invited to participate the study. If they pass the inclusion criteria and are willing to participate, they will be invited to come to the VUmc for a visit with the researcher. A final decision on eligibility will be made, based on the inclusion criteria. Participants will be assessed during a part of the day (maximum of three hours in study A, one hour in study B). In that time they will complete questionnaires and perform physical-performance tests, and walk on the treadmill with different gait modification conditions. To protect participants from falling, subjects will wear a safety harness during the walking trials. During the measurements, participants will be asked to modify the gait pattern. The risk of gait modification on side effects is negligible. Total risk of adverse events during the assessments and during walking on the treadmill is negligible. Also during the training, the risk on adverse events is negligible. Periods of rest will be allowed during/ between the measurements to prevent fatigue. Patients will also be asked about their pain levels and the training or measurements can be shortened if necessary in response to increasing pain (although from previous literature in the field we do not anticipate this problem). Patients will also be made aware that they are free to withdraw from the study at any time without giving a reason.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for the present study (A and B) are knee osteoarthritis on the medial compartment based on the ACR criteria, age between 50 and 75 years old, Body Mass Index (BMI) between 20 and 30 kg/m2, maximum score of 7 on the numeric rate scale (NRS) for pain intensity during the past two weeks.
Additional inclusion criteria for study B is satisfaction with applied gait modification pattern in study A, willingness to further learn this pattern and clear improvement in knee adduction moment (approximately 10% reduction). This will be at the discretion of the physiotherapist involved who will have the final decision on inclusion.

Exclusion criteria

Total knee replacement, rheumatoid arthritis or any other form of inflammatory arthritis (i.e., crystal arthropathy or septic arthritis). Similarly patients with hip osteoarthritis will be excluded, as will people with poor vision that would prevent them from being able to see the visual feedback. Patients who are already included in any other experimental research study (including but not limited to the Vitamin D study and the COOA study) will also be excluded.

Study design

Design

Study phase:	2
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2015
Enrollment:	41
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL51889.029.15