Walking Alteration for Knee osteoarthritis, the WALK study. An RCT*

Published: 22-11-2016
Last updated: 15-04-2024

To evaluate the effectiveness of the WALK gait retraining program, compared to a standardised treatment protocol based on the KNGF (royal Dutch association of physiotherapists) guidelines, in patients with clinical symptoms of mild to moderate knee...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON46305

Source
ToetsingOnline

Brief title
WALK study

Condition

- Joint disorders

Synonym
arthrosis, knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Cöoperatie Orthopedie

Intervention

Keyword: knee osteoarthritis, physical therapy, walk program

Outcome measures

Primary outcome

Between group difference in change in pain / function score between baseline and 3 months follow-up.

Secondary outcome

Secondary outcomes are OMERACT*OARSI set of responder criteria, KOOS, NRS pain, EQ-5D, ICOAP, *need for TKA* OARSI-criteria, gait parameters as assessed by gait analyses (duration of full extension and quadriceps muscle activity during midstance of walking cycle) , and medication use. To get more insight in which specific patients will respond on the current intervention also the HADS, Central Sensitization Inventory, pain drawing form and pain cognition list will be evaluated.

Study description

Background summary

Osteoarthritis (OA) of the knee is associated with changes in gait pattern. These changes result in a dysfunctional gait pattern, that by itself can worsen the OA symptoms. Main goal of the Walking ALteration for Knee osteoarthritis (WALK) gait correction program is to achieve full passive and active knee extension. This is a prerequisite for quadriceps relaxation in early mid stance in the gait cycle, thus reducing the tibiofemoral forces during a considerate period of the gait cycle. Our hypothesis is that adaptation of the gait pattern through gait retraining can relieve the symptoms in knee OA.

Study objective

To evaluate the effectiveness of the WALK gait retraining program, compared to

a standardised treatment protocol based on the KNGF (royal Dutch association of physiotherapists) guidelines, in patients with clinical symptoms of mild to moderate knee OA and a knee extension deficit. The hypothesis is that the WALK gait retaining program is more effective to treat patients with symptoms of mild to moderate knee OA (superiority study).

Study design

Open-labeled randomized controlled trial.

Intervention

Patients will be randomized in a) WALK gait retraining program or in b) physiotherapy with a standardised treatment protocol, in accordance with the Dutch guideline for physiotherapists on knee OA (usual care).

Study burden and risks

The WALK gait retraining program has been shown to have favourable effects on OA symptoms in mild to moderate knee OA in the WALK study pilot. This RCT is executed to compare this method to current physiotherapeutic intervention. Participating subjects will not be exposed to any additional risks.

Besides the treatment, subjects will undergo limited testing procedures; functional outcome is assessed with questionnaires, and measurements of gait parameters are performed with video based gait analysis, using adhesive markers on anatomical landmarks, and skin electrodes for surface EMG measurements.

Contacts

Public
Maxima Medisch Centrum

Ds Fliednerstraat 1
Eindhoven 5631 BM
NL
Scientific
Maxima Medisch Centrum

Ds Fliednerstraat 1
Eindhoven 5631 BM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Symptomatic knee OA according to the clinical ACR criteria
- Radiographic OA, according to Kellgren and Lawrence grade 1, 2 or 3
- Flexion contracture of 5 degrees or more, measured with a goniometer

Exclusion criteria

- Medial or lateral instability of the knee,
o Medial or lateral joint space opening of * 5 mm in 20° of knee flexion is considered as unstable.
- Symptomatic bilateral knee OA
- Intra-articular injection of the knee, in the previous 3 months
- Previous peri-articular osteotomy of the affected knee
- Symptomatic OA of hip or ankle
- Co morbidity which disables the function of the lower extremity
- Rheumatoid Arthritis or other inflammatory joint disease
- Physical therapy for current complaints during last 3 months
- Insufficient command of the Dutch language
- Legally incompetent adults

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	144
Type:	Anticipated

Ethics review

Approved WMO Date:	22-11-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	18-12-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL58142.015.16