The effects of physical activity pattern on disease progression in patients with knee osteoarthritis

Published: 14-09-2022
Last updated: 22-02-2025

Primary Objective:• To determine the impact of different types and intensities of physical activities, i.e. running, cycling, tennis and hiking, on the structural progression of knee OA in a group of early-stage knee OA patients.Secondary Objectives...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON51855

Source
ToetsingOnline

Brief title
LoaD

Condition

- Musculoskeletal and connective tissue disorders NEC

Synonym
early-stage knee osteoarthritis / knee arthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Osteoarthritis knee, Physical activity, Prognosis

Outcome measures

Primary outcome

Differences in structural progression of knee OA between the selected physical activities (running, cycling, tennis, and hiking) after 24 months follow-up, scored using our recently introduced definitions for longitudinal evaluation of OA MRI features.

Structural progression of knee OA: scored using recently proposed definitions by our research group for longitudinal evaluation of OA MRI features.
All subregional change scores (1 for progression, *1 for improvement and 0 for no change) will be summed over the different MRI Osteoarthritis Knee Score (MOAKS) subregions into an overall measure of change per feature.
The summed change scores per feature will consequently be dichotomized into progression versus no progression (change score >= 1 = progression, change score < 1 = no progression).

Secondary outcome

1. Differences in clinical progression of knee OA expressed as change on sub-scales of KOOS and patient nominated activity pain score between the selected physical activities (running, cycling, tennis, and hiking) after 24 months follow-up.

2. Association between GPS-based individual activity profiles and increased risk of knee OA progression

3. Interaction between inflammation (including inflammatory markers IL-6, CRP, proteomics and questionnaire data) and genetics and physical activity on the progression of clinical and structural knee OA

4. Interaction between physical activity and known risk factors for knee OA, on the progression of knee OA

5. Role of the microbiome on the progression of knee OA in different types of physical activities.

6. Interaction between daily activities and the progression of knee OA in different types of physical activities.

Study description

Background summary

Knee osteoarthritis (OA) is a chronic condition that is characterised by pain and impaired function and contributes hugely to physical disability on population level. With the growing elderly population worldwide, the prevalence of OA will increase and is estimated to be the number one chronic disease in the Netherlands in 2040.

There is an ongoing debate regarding the amount of exercise that is healthy for the joint, since specific types of loading can threaten the integrity of joint tissues and therefore develop or accelerate OA.
Some studies have tried to elucidate the association between sports activity and the progression of knee OA.

Unfortunately, there is no clear outcome so far and, to our knowledge, no prospective studies have been performed .
There is therefore urgent need to further investigate the impact of physical activity on the progression of knee OA.

Study objective

Primary Objective:
• To determine the impact of different types and intensities of physical activities, i.e. running, cycling, tennis and hiking, on the structural

progression of knee OA in a group of early-stage knee OA patients.

Secondary Objectives:
• To examine the impact of different types and intensities of physical activities (running, cycling, tennis, and hiking) on the clinical progression of knee OA in early-stage knee OA patients after 24 months.
• To examine associations between inflammation and physical activity on the progression of knee OA after 24 months.
• To investigate the role of genetics in the progression of knee OA in different types of physical activities (running, cycling, tennis, and hiking).
• To investigate the interaction between physical activity and known risk factors for knee OA, on the progression of knee OA.
• To investigate the role of the microbiome on the progression of knee OA in different types of physical activities.
• To investigate the interaction between daily activities and the progression of knee OA in different types of physical activities.

Study design

The study design is a prospective cohort study of 332 patients with early signs of knee OA who perform different types of physical activity (running, cycling, tennis or hiking).
Patients will be followed for a period of 24 months. The setting where the study will be designed and the data collected and handled is the Erasmus MC University Medical Center.

At baseline patients will fill out an online questionnaire, an MRI-scan of the knee will be made, a stoolsample collected, blood serum (e.g. IL-6, CRP, genetics) will be extracted, and a physical examination will be performed.

Hikers, runners and cyclists are requested to track their physical activity with a wearable GPS-device. This includes smartphone applications (e.g. Strava, Runkeeper, Wahoo, Garmin, sensor logger) or sports watches used during their physical activity. Data extracted will include time spent on physical activity session, distance and speed per activity.

All tennis players are asked monthly about the average number of hours played per type of game (singles vs doubles, free play vs training vs matches) and the most played surface (clay, smashcourt, grass/artificial grass, hardcourt, or indoor (carpet)) per week in the past month.

Patients will be asked to wear an activity monitor twice, for one week during the first and last half year of participation.

During follow-up, patients will receive a monthly questionnaire to collect information on the progression of the knee OA and a question for the hikers, runners and cyclists to share their GPS training data from the wearable

devices.
At 24 months follow-up patients will receive another MRI-scan of the knee, a physical examination, and blood serum (e.g. IL-6, CRP) will be extracted.

Study burden and risks

The study population will not be exposed to any risks. The burden of participation consists of completing a total of 25 online questionnaires (baseline approximately 20-30 minutes, monthly questionnaire approximately 5-10 minutes, 3-monthly questionnaire approximately 10-20 minutes), two examinations including a physical examination, blood samples, MRI-scan of the knee and a sinlge stoolsample collection. Each examination will take approximately 1 hour.

Additionally, they are all asked to track their physical activities using GPS wearable devices and register daily activities twice for one week using an activity monitor (Actigraph) based on accelerometry.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients (m/f) aged 45-65 years

Presence of non-traumatic knee complaints for at least three months

NICE guideline diagnosis of clinical knee OA (i.e. aged 45 or over and activity related joint pain and either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes)

Average physical activity level of the performed type of activity, which is their primary sport activity, in the last 6 months:
o Running: >= 60 minutes running per week
o Cycling: >= 120 minutes cycling per week
o Tennis: >= 1 hour (match and/or training session) per week
o Hiking: >= 1 hike of at least 10km per week

Exclusion criteria

Other pathological conditions that could explain knee complaints like traumatic onset knee complaints, presence of other forms of arthritis (rheumatoid arthritis, psoriatic arthritis), pre-patellar bursitis or patellar tendinitis

Onset of knee complaints > 24 months ago

Contraindications for MRI

No mobile phone or wearable device to track physical activity and unwilling to share tracked physical activity data.

Presence of any complaints other than knee OA resulting in physical impairment that will limit the physical activity

Unwilling to participate

No or insufficient knowledge of Dutch language

No access to e-mail

Surgery on the affected knee in the last six months

Planned surgery on the affected knee in the period of participation

Fulfilling the inclusion criteria for more than one of the four physical activities.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-10-2023
Enrollment:	332
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	11-02-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL81561.078.22