Exercise therapy in people with early-stage knee osteoarthritis: a feasibility study

Published: 08-03-2022
Last updated: 05-04-2024

The general aim is to identify the relevance and feasibility of a cost-effectiveness study on exercise therapy in patients with early stage knee OA1. What is the feasibility, in terms of percentage of eligible patients recruited, for GPs to recruit...

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

Summary

ID

NL-OMON51703

Source
ToetsingOnline

Brief title
Pilot ET knee OA

Condition

- Joint disorders

Synonym
knee arthrosis; knee osteoarthritis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cost-effectiveness, Exercise therapie, Feasibility pilot, Osteoarthritis knee

Outcome measures

Primary outcome

The primary outcomes of the pilot study will be:

1) the percentage of eligible patients recruited at GP practices during a

12-weeks inclusion period

2) the percentage of included (randomized and willing to participate)

participants during 12 weeks inclusion period

3) adherence: the number of exercise sessions followed by the participants in

the intervention group and, if applicable, adherence to home exercises

(measured with exercise adherence rating scale (EARS), and

4) patient reported outcome measures at 12 weeks follow-up, including mean pain

intensity during last month and mean pain during activity [11-point Numerical

Rating Scale (NRS)], Patient Acceptable Symptom State (PASS), flares, Knee

injury and Osteoarthritis Outcome Score (KOOS), Quality of life (EQ-5D),

Patient*s Global Assessment (PGA) (related to their knee), and self-efficacy

for exercise (SEE)

Secondary outcome

Not applicable

Study description

Background summary

There is increasing emphasis in the literature on the identification and initiation of treatment of Osteo Arthritis (OA) in the very early stage of the disease. Exercise therapy is the number one treatment for knee OA patients in primary care and the effectiveness for this intervention is clear and robust. As most studies have included patients with well-established complaints of knee OA, the exact magnitude of the effect in a group with early-stage knee OA remains unclear.
In an early-stage of disease, patients often report complaints periodically. For this reason, people with early stage OA, treated or not, might hugely recover at short-term. Defining relevant outcome measures when assessing such early stage treatment is therefore challenging.

Therefore, with this pilot-study we will investigate which clinical outcome will be most suitable to be used in the large-scale cost-effectiveness Randomized Clinical Trial (RCT).

From a practical point of view, barriers might exist for both General Practitioners (GPs), as well as for patients with regard to the early treatment, which currently remain unknown. One important issue that needs to be explored is the willingness of GPs to refer patients in a very early stage of the disease to a Physiotherapist (PT) for exercise therapy.

As this is not common practice, and GPs often apply a wait-and-see strategy in this stage of the disease, a change in daily practice is mandatory.

Therefore, the feasibility of patient recruitment should be investigated, not only from the perspective of GPs, but also from patients: i.e. are patients in this stage of the disease ready for a referral to a PT and will they adhere to the prescribed intervention? Symptoms are often still mild to moderate in this phase of the disease and will patients therefore be motivated enough to follow an exercise program? These feasibility questions first need to be answered before a large-scale cost-effectiveness RCT can be set up.

Study objective

The general aim is to identify the relevance and feasibility of a cost-effectiveness study on exercise therapy in patients with early stage knee OA

1. What is the feasibility, in terms of percentage of eligible patients recruited, for GPs to recruit patients with early-stage knee OA into a RCT of exercise therapy compared to usual care?
2. What percentage of eligible patients are willing to participate in the study in terms of randomization and willingness to start exercise therapy?
3. How well do participants adhere to exercise therapy (i.e. number of exercise therapy sessions) in the intervention group?
4. What is the most suitable clinical outcome measure to be used in a future

large-scale RCT exploring the cost-effectiveness of exercise therapy compared to usual care in patients with early-stage knee OA?

Study design

To study the feasibility of recruitment, the willingness to participate, the compliance of the participants towards the intervention and the most suitable outcome measure to use, we will perform a two parallel arm pilot randomized controlled trial with a follow-up of 12 weeks.

Procedure:
We will recruit a minimum of 3 large GP practices via the academic general practitioner network PRIMEUR. Patients who consulted their GP in the previous 12 months, or consult their GP for knee complaints during the inclusion period will be invited to participate in the study.

In addition, potential candidates are also recruited through open recruitment through advertisements.

They will be given information about the study and study procedures. Patient who are willing to participate, will be randomized into the intervention (exercise therapy by PT in addition to usual care by GP) or control (usual care by GP) group (after informed consent and baseline measurement).
Block randomisation will be used with random blocks of 4 or 6 patients.
Blinding for subsequent treatment of patient, care provider and researcher during follow-up will not be possible. All participants will receive two follow-up questionnaires, after 6 and 12 weeks of follow-up.

Exercise therapy, supervised by a PT, will be performed following the guidelines for knee OA of the Royal Dutch Society for Physiotherapy. Physiotherapists will be trained to aim for increasing training intensity during the treatment.

Patient selection: Patients will be selected from the medical file records of the GPs. If interested, patients will be screened by telephone using the NICE criteria for the diagnosis of clinical knee OA, as presently used in GP practice.

Intervention

Intervention:
Exercise therapy supervised by a PT according to a protocol based on the Dutch guideline for physiotherapy in addition to usual care by GP.

The exercise therapy treatment will focus on strengthening, endurance and functioning, and when needed neuromuscular balance and range of motion, and

will be tailored to the patient*s capacity. Participating PTs will be instructed during a consensus meeting, as also was done in our previous research projects. The exercise therapy will consist of maximal 12 treatment sessions during the first 12-weeks of follow-up and will be administered by PTs.

Control intervention:
The control group will receive a folder with information on osteoarthritis and what they can do themselves to decrease complaint.

Subject level:
All participants will be asked to complete a baseline questionnaire and two follow-up questionnaires at 6 and 12 weeks follow-up. The package will raise questions related to:
• Demographics (age, sex, height, weight, education level, ethnicity, health literacy);
• Lifestyle (physical activity (IPAQ-S)
• Adherence of exercise therapy (EARS)
• Knee complaints (VAS pain, KOOS, PGA)
• Quality of life (EQ-5D)
• Self-efficacy for exercise (SEE).

Moreover, willingness of participation of eligible patients from the GP medical file records will be registered.

GP level:
Registration of
• number of GPs that are willing to participate
• number of potential eligible patients per GP practice
• percentage of eligible patients that already received exercise therapy for knee complaints

Physiotherapy level:
Registration of
• participant adherence during intervention period, including
o number of sessions and
o performance of home-exercises using a registry form

Study burden and risks

For the participants randomized to the intervention group (standard care plus exercise therapy), the load consists of the weekly exercise therapy sessions, the exercises at home and the completion of questionnaires three times.

The expected benefit for this group is a reduction in knee complaints, due to muscle strengthening, such as a reduction in pain during activity, an improvement in pain intensity, and therefore a better quality of life.

There is no direct benefit for participants randomized to the control arm (standard care).

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)
Elderly (65 years and older)

Inclusion criteria

Patients (m/v) aged 45 years or older

1st GP consult with non-traumatic knee complaints within 12 months prior to the search in the medical file records of the GPs

Diagnosis according NICE criteria
• >=45 years of age
• activity related knee pain

• no morning stiffness or <= 30 min

Duration of knee complaints at the time of a GP visit should be less than 12 months

Exclusion criteria

Previous treatment with exercise therapy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2022
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	08-03-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-06-2022

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-09-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-11-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-12-2022
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	NL79279.078.21