Optimization of exerCise Therapy in patients with knee Osteoarthritis in a Primary care Setting (OCTOPuS-study)

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The present project aims to evaluate the effectiveness and cost-effectiveness of stratified exercise therapy, compared to usual care, in patients with knee OA treated by PTs in primary care.

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

Summary

ID

NL-OMON48786

Source
ToetsingOnline

Brief title
OCTOPuS

Condition

- Joint disorders

Synonym
knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: KNGF (beroepsorganisatie voor fysiotherapeuten)

Intervention

Keyword: cluster randomized controlled trial, dietary treatment, exercise therapy, knee osteoarthritis, physical therapy

Outcome measures

Primary outcome

Knee pain severity (NRS) and physical functioning (KOOS subscale daily living) will be primary outcome measures. Measurements will be performed at baseline, and 3 months (primary endpoint), 6 months and 12 months follow-up.

Secondary outcome

Secondary outcome measures includes global perceived effect (GPE), pain interference, fatigue, and knee instability (questionnaires), and upper leg muscle strength, body mass index (BMI), and waist circumference (physical tests). In addition, an economic evaluation (by patient-reported costs and quality-adjusted life years (QALYs)) and a process evaluation (by treatment registration forms) will be performed. Measurements will be performed at baseline, and 3 months (primary endpoint), 6 months (questionnaires only), 9 months (cost questionnaires only) and 12 months follow-up.

Study description

Background summary

Knee osteoarthritis (OA) is a highly heterogeneous disease, in which exercise therapy by a physical therapist (PT) is recommended as a first-step, conservative treatment. Nonetheless, the clinical effects of exercise therapy are only modest, which may be attributed to a generic, *one-size-fits-all* approach. Because of the large heterogeneity of knee OA with large differences between patients, a stratified approach in exercise therapy, meaning that patients are allocated to subgroups and receive a subgroup-specific

intervention, may be superior over usual exercise therapy. Recently, we were able to identify clinically relevant subgroups of knee OA patients, developed a model of stratified exercise therapy based on these subgroups, and tested its feasibility in a pilot-study. Therefore, it is timely to evaluate the effectiveness and cost-effectiveness of stratified exercise therapy compared to usual (*non-stratified*) care by PTs in a large-scale cluster randomized controlled trial (CRCT).

Study objective

The present project aims to evaluate the effectiveness and cost-effectiveness of stratified exercise therapy, compared to usual care, in patients with knee OA treated by PTs in primary care.

Study design

A pragmatic, cluster randomized controlled trial (CRCT) with an economic and a process evaluation, comparing stratified exercise therapy with usual care by PTs in primary care. Approximately 120 PTs from 60 PT practices in a primary care setting (at least 2 participating PTs per practice) will be randomized on the level of PT practice in a 1:2 ratio to provide the experimental intervention (stratified exercise therapy for 204 patients; by 40 PTs/20 practices) or control intervention (usual care for 204 patients; by 80 PTs/40 practices), respectively.

Intervention

The model of stratified exercise therapy for PTs consists of a stratification tool and subgroup-specific, protocolized exercise therapy. Based on the stratification tool, patients will be allocated to a *high muscle strength subgroup*, *low muscle strength subgroup*, or *obesity subgroup*. For the *obesity subgroup*, a dietary treatment by a dietician in primary care will be provided, in addition to the exercise therapy. The control intervention will be usual care from the PT.

Study burden and risks

All patients (from both treatment arms) will be treated by their PT, with clinical effects and minimal risks to be expected. In the pilot-study (n=50), no adverse events occurred. The burden of the patients will be minimized to the time necessary for completing the questionnaires and tests.

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

- knee pain (NRS during walking * 2/10) persisting for at least 3 months, as reason to visit the PT;
- clinical diagnosis of knee OA according to the criteria of the American College of Rheumatology (ACR), assessed by the PT: presence of knee pain and at least three of the following six items: age > 45 years, morning stiffness < 30 minutes, crepitations, bone sensitivity, bony enlargement of the joint margin, no palpable warmth;
- providing informed consent.

Exclusion criteria

- age < 40 or > 85 years;
- severe knee pain (i.e., NRS pain severity during walking * 9/10);
- physical or mental comorbidity severely affecting daily life and a contraindication for the usage of exercise therapy;
- suspicion of chronic widespread pain (i.e., pain present for at least three months in at least three joints including left and right side of the body, above and below the waist and the axial skeleton);
- presence of total knee arthroplasty (TKA) or on waiting list for TKA;
- other reasons for knee pain than knee OA (e.g., rheumatoid arthritis, gout)
- received PT-treatment or intra-articular injections in past 6 months because of knee pain;
- insufficient comprehension of Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-01-2019
Enrollment:	408
Type:	Actual

Ethics review

Approved WMO

Date:	16-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	25-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-10-2019
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

ID: 22196
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66769.029.18
OMON	NL-OMON22196