Onderzoek naar verbeteren van fysiotherapiebehandeling bij knieartrose

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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 on knee pain and...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22196

Bron
NTR

Verkorte titel
OCTOPUS

Aandoening

Knee osteoarthritis

Ondersteuning

Primaire sponsor: VU Amsterdam, Department of Health Sciences
Overige ondersteuning: Wetenschappelijk College Fysiotherapie (WCF) of Royal Dutch Society for Physical Therapy (KNGF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Knee pain severity, assessed by a Numeric Rating Scale (NRS) for knee pain on average

during walking in the past week (1 item; score between 0 and 10; 0= no pain; 10= worst pain imaginable).
- Physical functioning, assessed by subscale function in daily living (ADL) of the Dutch translation of the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire (17 items; score between 0 and 100; 0= maximal problems; 100= no problem)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 on knee pain and physical function 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).

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. PT practices in a primary care setting (n=60, with 2 participating PTs per practice) will be randomized in a 1:2 ratio to provide the experimental or control intervention, respectively.

Study population: 408 eligible patients with diagnosed knee OA visiting a participating PT because of persisting knee complaints.

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 intervention 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.

Main study parameters/endpoints: Knee pain severity (NRS) and physical functioning (KOOS subscale daily living) will be primary outcome measures. Secondary outcome measures include 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) and 12 months follow-up, with an additional cost questionnaire at 9 months.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All patients (from both treatment arms) will be treated by their own 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.

Doel van het onderzoek

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 on knee pain and physical function 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). The OCTOPUS-study 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.

Onderzoeksopzet

Primary and secondary outcome measures will be assessed at baseline (t0) and 3 months (t3;

primary endpoint), 6 months (t6) and 12 months follow-up (t12). In exception to this, the physical tests (muscle strength, BMI and waist circumference) will not be assessed at t6 and an additional economic evaluation will be assessed at 9 months follow-up (t9). Furthermore, process information on the content, intensity and volume of the intervention will be assessed through registration forms after each treatment sessions by the PT and dietician. Finally, qualitative information on treatment feasibility will be collected after the inclusion period through (semi-structured) interviews with ‘topic lists’ in a random sample of patients from both treatment arms (n=20), PTs from both treatment arms (n=10) and dieticians (n=5).

Onderzoeksproduct en/of interventie

The experimental intervention will be a model of stratified exercise therapy for PTs. This model 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’. Each of these subgroups will receive subgroup-specific, protocolized exercise therapy. For the ‘obesity subgroup’, a dietary intervention 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.

Contactpersonen

Publiek

Vrije Universiteit Amsterdam
Jesper Knoop

020-5989491

Wetenschappelijk

Vrije Universiteit Amsterdam
Jesper Knoop

020-5989491

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- knee pain (NRS during walking >= 2/10) persisting for at least 3 months as their reason to visit the PT;

- clinical diagnosis of knee OA according to the criteria of the American College of Rheumatology, assessed by the PT, which is: 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 or intra-articular injections in past 6 months because of knee pain;

- insufficient comprehension of Dutch language.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-01-2019
Aantal proefpersonen:	408
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-01-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48786
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7463
NTR-old	NTR7705
CCMO	NL66769.029.18
OMON	NL-OMON48786

Resultaten

Samenvatting resultaten

- Knoop J, et al. Identification of phenotypes with different clinical outcomes in knee osteoarthritis: data from the Osteoarthritis Initiative. Arthritis Care Res (Hoboken) 2011;63(11):1535-1542.
- van der Esch M, et al. Clinical phenotypes in patients with knee osteoarthritis: a study in the Amsterdam osteoarthritis cohort. Osteoarthritis Cartilage. 2015 Apr;23(4):544-9.
- Knoop J, et al. Knee joint stabilization therapy in patients with osteoarthritis of the knee: a randomized, controlled trial. Osteoarthritis Cartilage 2013;21(8):1025-34.
- de Rooij M, et al. Efficacy of Tailored Exercise Therapy on Physical Functioning in Patients With Knee Osteoarthritis and Comorbidity: A Randomized Controlled Trial. Arthritis Care Res (Hoboken). 2017 Jun;69(6):807-816.
- Knoop J, et al. Is a model of stratified exercise therapy by physical therapists in primary care feasible in patients with knee osteoarthritis? Under review.