Lifestyle intervention trial in early stage knee osteoarthritis

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

Samenvatting

ID

NL-OMON24915

Bron
NTR

Verkorte titel
LITE

Aandoening

Knee osteoarthritis

Ondersteuning

Primaire sponsor: Erasmus MC University Medical Center Rotterdam, Department of General Practice
Overige ondersteuning: ZonMw (5550003207) and ReumaNederland (ZNW 20-501)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcomes include a 5 kg or 5% weight reduction at 24 months follow-up, clinical

progression (mean pain intensity during the last month (11-point NRS) over 24 months of follow-up), structural progression on MRI at 24 months follow-up (MOAKS: change of individual MOAKS features per subregion and summed change per MOAKS features), and health-related quality of life measured with the EQ-5D-5L over 24 months.
For the cost-effectiveness analysis, societal costs over 24 months using the medical consumption and productivity cost questionnaire (iMCQ and iPCQ) will be evaluated.

Toelichting onderzoek

Achtergrond van het onderzoek

Obesity is an important risk factor for knee osteoarthritis (OA). Hence, weight loss is recommended in many international guidelines for the treatment of overweight or obese patients with knee OA. Especially in the early stage of the disease, weight loss is important to prevent further clinical and structural progression. Since 2019 in the Netherlands, general practitioners (GP) can refer eligible patients to a combined lifestyle intervention (GLI) focused on exercise, nutrition, and behavioral change. However, GPs scarcely refer patients with knee OA because of the unfamiliarity with the intervention, unawareness of the target group with OA, and lack of scientific evidence on the (cost-)effectiveness. Also, for successful implementation of the lifestyle program insight into perceived facilitating factors and barriers, as in individual and environmental determinants are required. The aim of this study is to determine the (cost-)effectiveness of a combined lifestyle intervention in early stage knee OA patients in primary care.

Doel van het onderzoek

We hypothesize that a combined lifestyle intervention added to usual care will result in a 5 kg or 5% weight reduction resulting in a greater reduction in knee pain, an increase in the quality of life, prevent structural progression, and is cost-effective from a societal perspective compared to usual care only.

Onderzoeksopzet

All participants will be sent 3-monthly questionnaires and invited for a physical examination, blood sampling, and MRI assessment at baseline and after 24-month follow-up.

Onderzoeksproduct en/of interventie

Multidisciplinary lifestyle interventions with a focus on diet and exercise show large potential for the treatment of knee OA. The 2-year lifestyle intervention (Beweegkuur-GLI) program is based on the combination of diet, increased physical activity (PA), and behavior modification. The general aim of the Beweegkuur-GLI is to lose at least 5% of body weight during the first year and to maintain this weight loss in the second year. Participants will be randomly allocated to either the combined lifestyle intervention program in combination with usual

care or usual care only. Patients in the intervention group will be referred to a certified lifestyle coach to participate in the Beweegkuur-GLI. During the intervention patients will be supported by a team of health care professionals, including the lifestyle coach, a physical therapist, and a dietician. Patients in the control group will receive usual care by their GP following the NHG guideline non-traumatic knee complaints.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients aged between 45 and 70 years, a BMI of 25 kg/m2 or higher, diagnosis of clinical knee OA (according to NICE guidelines), and a first presentation at their general practitioner with knee complaints within the previous 24 months will be included.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Other pathological conditions that could explain the joint complaints like traumatic onset knee complaints or presence of other forms of arthritis (rheumatoid arthritis, psoriatic arthritis), pre-patellar bursitis or patellar tendinitis;
- Any lower extremity condition other than KOA resulting in physical impairment that will limit GLI participation.

- Previously participated in a combined lifestyle intervention (GLI);
- Contraindications for MRI;
- Not being able to speak, read or write Dutch.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	234
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
OA Trial Bank

Ethische beoordeling

Positief advies

Datum:	23-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9355
Ander register	METC Erasmus MC : MEC-2020-0943

Resultaten

Samenvatting resultaten
N/A