Lifestyle intervention trial in early stage knee osteoarthritis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24915

Source
NTR

Brief title
LITE

Health condition

Knee osteoarthritis

Sponsors and support

Primary sponsor: Erasmus MC University Medical Center Rotterdam, Department of General Practice
Source(s) of monetary or material Support: ZonMw (5550003207) and ReumaNederland (ZNW 20-501)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Patients' reported severity of knee pain and activity limitations evaluated over 24 months with the Knee injury and Osteoarthritis Outcome Score (KOOS); the severity of intermittent and constant osteoarthritis pain (ICOAP); the global rating of change (GRoC); Patient Acceptable Symptom State (PASS); and mean pain intensity during the last month (11-point NRS) over the last 12 months of follow-up. Moreover, general health outcomes including blood pressure, HbA1c levels, and cholesterol are evaluated at 24 month follow-up.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

- 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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2021
Enrollment:	234
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
OA Trial Bank

Ethics review

Positive opinion

Date:	23-03-2021
Application type:	First submission

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
NTR-new	NL9355
Other	METC Erasmus MC : MEC-2020-0943

Study results

Summary results
N/A