The (cost-)effectiveness of a combined lifestyle intervention in overweight and obese patients with knee osteoarthritis in primary care

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The general aim of this project is to determine the clinical and cost-effectiveness of a combined lifestyle intervention, in addition to usual care, in early stage knee OA patients with overweight/obesity in comparison with usual care. Primary…

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

Summary

ID

NL-OMON54019

Source
ToetsingOnline

Brief title
Lifestyle and knee OA

Condition

- Joint disorders

Synonym
Knee osteoarthritis; layman: Knee arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMw,ReumaNederland

Intervention

Keyword: Cost effectiveness, Lifestyle intervention, Osteoarthritis knee

Outcome measures

Primary outcome

5kg or 5% weight reduction after 24 months

Secondary outcome

Secondary study parameters/endpoints

1. Clinical progression of knee OA: decrease in monthly mean pain intensity

(11-point NRS) over last 12-months of follow-up

2. Structural progression of knee OA on MRI after 24 months, using our recently

introduced definitions for longitudinal evaluation of OA MRI features

For cost-effectiveness:

1. Societal costs over 24 months, using the medical consumption and

productivity cost questionnaire (Medical Consumption Questionnaire (iMCQ) and

iPCQ questionnaires).

2. Quality of life after 24 months (EQ-5D-5L)

Other study parameters

1. Other disease specific PROMS (subscales KOOS questionnaire, PASS, GROC)

2. Other health outcomes including HbA1c level (mmol/L), cholesterol (mmol/L),

blood pressure, and intestinal microbiota after 24 month follow-up

3. Psychosocial health outcomes in terms of kinesiophobia and self-efficacy

for exercise

Qualitative interviews

4. (Gender- and sex-specific) Barriers and facilitators of patients for the

implementation of the GLI for patients with KOA.

Primary mediators that will be investigated on structural and clinical

progression of knee OA:

- Change in BMI during the first 18-months of follow-up

- Meniscal extrusion using two-dimensional quantitative measurements

- Biomarkers

- Inflammatory markers including IL-6 and CRP

- Effusion, using MOAKS scoring[23], on MRI

Study description

Background summary

Knee osteoarthritis (OA) is a chronic condition characterized by pain and impaired function and strongly contributes to physical disability. With an aging population, the prevalence of OA is estimated to be the number one chronic disease in the Netherlands in 2040. A high BMI is a major risk factor for knee OA, but also considered the most modifiable risk factor for knee OA.. In those with established knee OA in secondary care, there is evidence that weight loss has notable effects on pain and function. Many international guidelines therefore recommend 5 to 10% weight loss for knee OA patients if overweight or obese.

The importance of a healthy lifestyle for people with overweight has received considerable attention. What is not yet clear is the effect of sex- and gender on making lifestyle choices, the preference for a lifestyle program, or adherence to a lifestyle program. In addition, weight loss in women might have

different effects on knee OA development and/or progression than weight loss in men. These differences between men and women must be considered to improve health care.

In the Netherlands, a combined lifestyle intervention (i.e. beweegkuur) was developed in 2007 by the Netherlands Institute for Sport and Physical Activity, commissioned by the Dutch ministry of Health, Welfare and Sports, with the aim to treat and prevent diabetes mellitus type 2. Further development and refinement made the beweegkuur available for patients with overweight and obesity. However, it is only since 2019 that it is possible for GPs to refer eligible patients to a combined lifestyle intervention (e.g. *Beweegkuur*, *Slimmer*, Cool*). Eligible for referral are patients that have overweight or obesity and additional risk factors for cardiovascular diseases, diabetes type 2, or presence of sleep apnea or OA. Participation is only possible with a referral by the GP or medical specialist. The costs for the combined lifestyle intervention are for eligible patients since 2019 covered by the basic health insurance that all Dutch inhabitants have.

However, the (cost-)effectiveness of this intervention in the OA target population and in the primary care in the Netherlands has not yet been investigated. Therefore, the main aim of the described project is to investigate the (cost-)effectiveness of a combined lifestyle intervention in early knee OA patients in primary care. The search for (gender- and sex-related) factors that may mediate the effects of diet and exercise on clinical and structural outcomes will help to optimize and design optimal effective interventions where mechanisms of action are targeted.

Study objective

The general aim of this project is to determine the clinical and cost-effectiveness of a combined lifestyle intervention, in addition to usual care, in early stage knee OA patients with overweight/obesity in comparison with usual care.

Primary Objective:
1. To determine the effectiveness of a lifestyle intervention in primary care in early stage knee OA patients with overweight/obesity on the mechanistic outcome weight loss after 24 months.

Secondary Objective(s):
1. To determine the cost-effectiveness of a lifestyle intervention compared to usual care in primary care in knee OA patients with overweight/obesity after 24 months from a societal perspective
2. To determine the effectiveness of a lifestyle intervention in primary care in early stage knee OA patients with overweight/obesity on the clinical and structural progression of knee OA after 24 months
3. To explore potential working mechanisms for the change in both clinical and

structural features of knee OA within a 24 month time frame
4. To determine whether a lifestyle intervention in an OA population has positive side effects on HbA1c level (diabetes mellitus), cardiovascular risk factors (cholesterol, blood pressure and kidney function), and the intestinal microbiota after 24 months.

Study design

A pragmatic randomized controlled trial (RCT) among patients with early signs of knee OA in general practice and a Body Mass Index (BMI) >=25 kg/m2 with a follow-up of 24 months. Participants are randomized to either a lifestyle intervention program + usual care or usual care alone.

Randomisation:
The randomization sequence will be determined by an independent researcher from the department, with the use of a computer generated randomisation list. This sequence is secret for all involved researchers of the study. When patients are eligible for inclusion and completed the informed consent procedure, the baseline measurement takes place. Hereafter, the patients will be randomly allocated to one of the two groups by a researcher:
1) Usual care + combined lifestyle intervention
2) usual care alone

Procedures:
If the patient fulfils the inclusion criteria after prescreen and is willing to participate, he or she will be sent a written informed consent form and a baseline questionnaire by email.
After written consent the patients will be invited for a baseline visit for physical examination (including blood collection) and a Magnetic Resonance Imaging (MRI) of the symptomatic knee. Patients will be asked to collect a fecal sample in a collection tube and hand the sample in during the baseline visit.

Following the baseline assessments, the patients will be randomized (refer to above) into two groups.

All participating patients will be sent 3-monthly questionnaires and after 24 months follow-up all will be asked to collect a fecal sample and will be invited again for a physical examination and MRI of the knee.

Following the 2-year intervention, 30 patients will be invited to participate in qualitative interviews. All the interviews will be audiotaped and transcribed verbatim.

All participants will be asked for consent to contact them again after this study period since we additionally aim for a long-term follow-up (follow-up

after the two-year intervention terminated) of this patient population.

Intervention

All patients will receive usual care by their GP following the NHG guideline non-traumatic knee complaints. This includes advice for regular physical activity (at least 30 minutes a day) and advice to lose weight if the patient has a BMI>=25 kg/m2. Moreover, pain medication is considered and patients may be referred to a physical therapist when they fail to get enough exercise themselves.

Patients randomized to Arm 1, the intervention group will, in addition to usual care, be referred to a certified lifestyle coach for the *Gecombineerde Leefstijl Interventie* (Beweegkuur-GLI).

Combined lifestyle intervention:
The Beweegkuur-GLI has three primary aims
1. Exercise: encouragement towards physical activity and/or increase physical activity
2. Nutrition: Decrease energy intake by an individual diet, that will lead to an improvement of eating behaviour
3. Behavioural change: Support of self-management in lifestyle changes
During the entire trajectory, participants will be supported by a team of health care professionals, in which the lifestyle coach has the central role. Next to the lifestyle coach, there is involvement of a physical therapist, dietician, a neighbourhood sport coach and possible local sport services. 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.

Support of self-management:
Within the Beweegkuur-GLI, self-management is seen as the individual ability of the participant to deal with symptoms, physical, psychological and social consequences of a weight related health risk and to adjust their lifestyle of this. The degree of self-management is different for every participant of the program. The general model self-management guides the lifestyle coach on how to support the participant.

Support and coaching (Motivational Interviewing (MI)):
MI forms an essential part of the Beweegkuur-GLI and is defined as a directive person-centred support style in order to stimulate a change of behaviour by ambivalence compared to help to clarify and solve changes. The essence of MI is that the motivation for change comes from the participant itself instead of from the health care professional. The lifestyle coach will use the stages of change model, including the five motivational stages, as a core guidance.

Lifestyle coaching:
The Beweegkuur-GLI starts with an individual intake with the lifestyle coach,

followed by seven individual sessions of 30 minutes in the first year of the program. Bi-weekly group sessions are scheduled in the second quarter of year one.
During year two, five individual sessions are scheduled with the lifestyle coach.

Exercise component:
The physical therapist will, during an individual session, set up an individual exercise program at the start of the program. Additionally, two group sessions will take place in the first quarter of year 1, that aim to stimulate physical activity and discusses the aims and goals, including the stimulation to continue the physical activities after this period within the local sport and physical activity services. During year two there is continued coaching of the community sport coach or physical therapist.

The general aim of the exercise component is to reach a minimum of 1200 kilocalories energy expenditure per week, but optimally 2000 kcal/week. A gradual increase towards this dose is seen as most effective. There is a specific manual for physical therapists working with the Beweegkuur-GLI (*Document BeweegKuur voor de fysiotherapeut*) that leads physical therapist to all phases and decisions.

Nutrition component:
The dietician delivers the nutritional support and the lifestyle coach takes care of the follow-up on the advices of the dietician. The nutritional advices are provided following:
• NDF (Dutch Diabetes Federation) nutrition guidelines (2015) for diabetes patients
• Guideline Diagnostics and treatment of obesity in adults with a BMI>30
• Guidelines healthy nutrition as formulated by the Dutch Health Council for adults with a BMI >=25 and <=30
The program consists of individual consultations with the dietician and group education. All participants start with an individual session at the dietician and three group sessions during the first year. The content of the individual session, that will take place in the first quarter of year one, consist of extensive diagnostics, formulate a joint plan of treatment (participation in group sessions, maximum of 3 hours of follow-up consultations, individual diet), information on nutrition and behaviour that relates to OA. The three group education sessions (60 minutes, maximum of 12 participants) are planned in the first year. These primarily focus on increase of knowledge, improvement of skills, deal with high risk situation, control eating behaviour and contact with other patients. There is a specific manual for dieticians working with the Beweegkuur-GLI (*Document BeweegKuur voor de diëtist*) that leads dieticians to all phases and decisions. The lifestyle coach will be accompanying the dietician at the first group session. In year two, another three group sessions (60 minutes) will take place with the dietician.

Study burden and risks

All patients will receive care as usual provided by the general practitioner, so no changes in outcomes are expected in the control group, compared to normal subjects not participating in this study.

The patients allocated to the intervention group are likely to benefit of the intervention: A systematic review showed that 5 to 10% weight loss produces small positive effects on pain, self-reported disability and quality of life in adults with mild to moderate knee OA.

The burden for all patients participation in this study is the time needed to fill in the 9 questionnaires (baseline approximately 10-15 minutes, follow-up each approximately 5-10 minutes), collection of fecal samples (each approximately 5 minutes), and two examinations including a physical examination, blood samples and MR Imaging of the knee.
Each examination will take approximately 1 hour.

30 patients will participate in the semistructured interviews, therefore the burden of participation will be higher. The interviews will take a maximum of 60 minutes. Depending on the patient's preference, interviews will be conducted face-to-face in the Erasmus MC, at the patient's home, or online.

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

o First presentation at GP of knee complaints within previous 24 months
o Aged between 45 and 70 years
o NICE guideline diagnosis of clinical knee OA
(i.e. aged 45 or over and activity related joint pain and either
no morning joint-related stiffness or
morning stiffness that lasts no longer than 30 minutes)
o Presence of overweight or obesity (BMI >=25 kg/m2)

Exclusion criteria

o 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) or
pre-patellar bursitis or patellar tendinitis
o Any lower extremity condition other than knee OA resulting in physical
impairment that will limit GLI participation.
o Contraindications for MRI
o Previously participated in a GLI.
o Inability to understand the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-07-2021
Enrollment:	234
Type:	Actual

Ethics review

Approved WMO Date:	01-04-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-06-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-08-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-11-2021

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-01-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2023
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	NL75367.078.20