Plants for Joints RA

Gepubliceerd: 17-06-2019 Laatst bijgewerkt: 19-03-2025

A 16-week multidisciplinary lifestyle program, based on (1) a WFPD, (2) exercise and (3) stress management H0: has no effect on the disease activity in patients with rheumatoid arthritis, in comparison with usual care. H1: lowers disease activity...

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

Samenvatting

ID

NL-OMON19881

Bron
NTR

Verkorte titel
Plants for Joints RA

Aandoening

Rheumatoid arthritis

Ondersteuning

Primaire sponsor: Reade, Duyvensz-Nagel Stichting, Dr. Jan van Breemen Stichting, Stichting Vermeer 14, ZonMw
Overige ondersteuning: Own/private sources & public sources (ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main endpoint for RA-patients is the difference between mean change in DAS28 scores from 0-16 weeks (measured blind by a research nurse) in the intervention and control groups.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
An unhealthy lifestyle is associated with a higher risk of chronic diseases and conditions such as rheumatoid arthritis (RA). Low-grade inflammation is often present in people with unhealthy lifestyles and may be a key factor in the pathogenesis of chronic inflammatory diseases. Current treatment of RA mainly consists of medication. Combining different types of non-pharmacological therapies such as diet, exercise and stress management has shown synergizing effects in other chronic diseases. Whole foods plant-based diets (WFPDs) have shown promising results for the treatment of RA but were not yet combined with other lifestyle interventions.

Objective:
To investigate the effect of a multidisciplinary lifestyle program, based on a WFPD, exercise and stress management on disease activity in patients with RA. A one-year extension study will investigate continued adherence to lifestyle changes and measure to what extent it is possible to taper drug therapy for RA-patients in (near) remission.

Study design:
A 16-week randomized single-blind controlled trial (RCT), comparing a multidisciplinary lifestyle program with usual care in patients with active RA (n=80). The control group will be placed on a waiting list to receive the intervention after 16 weeks. After completion of the lifestyle program, all patients will be followed in a two-year extension study.

Study population:
RA patients with low to moderate disease activity (2.6≤DAS28≤5.1) and no or unchanged DMARD treatment for at least 3 months.

Intervention:
Personal counselling on diet and exercise, followed by 10 meetings in groups of 15 people with theoretical and practical training on a WFPD, exercise and stress management. The control group receives usual care. During the 16-week program the medication remains unchanged. During the one-year extension program subjects have 6 additional group meetings and – if in (near) remission – medication will be tapered in a standardized manner.

Main study parameters/endpoints:
The primary outcomes are: difference in mean change between intervention- and control group for the DAS28. For the two-year extension study the change in adherence from 0-24 months is the main endpoint.

Doel van het onderzoek

A 16-week multidisciplinary lifestyle program, based on (1) a WFPD, (2) exercise and (3) stress management

H0: has no effect on the disease activity in patients with rheumatoid arthritis, in comparison with usual care.
H1: lowers disease activity in patients with rheumatoid arthritis more than usual care.

Onderzoeksopzet

Start RCT: May 2019. End RCT: summer 2021. End extension study: summer 2023.

Onderzoeksproduct en/of interventie

During the first visit, subjects will be randomized and baseline measurements will be taken. The first visit will be concluded with a personal intake meeting with a registered dietician and a physiotherapist to determine personal objectives (i.e. weight loss), as well as abilities and limitations regarding exercise.

During the 16-week lifestyle program subjects will meet 10 times (weekly from week 1-9 and the last meeting in week 13, with minor rescheduling in case of holidays) in groups of maximum 15 people. Participants are invited to bring their partner/spouse (or someone else who is able to support the patient in this program) to the first meeting (cooking class).

During all meetings (duration 2- 3 hours) subjects will receive theoretical and/or practical training, based on protocols tested in previous studies on the following topics:
1. Whole foods plant-based diet (e.g. workshops cooking).
2. Exercise (e.g. brisk walking and/or muscle strengthening exercises), based on the Dutch physical activity guidelines 2017.
3. Stress management (e.g. relaxation exercises).

Contactpersonen

Publiek

Reade
Wendy Walrabenstein

+31658869219

Wetenschappelijk

Reade
Wendy Walrabenstein

+31658869219

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients ≥ 18 years.
Rheumatoid arthritis (RA) with low to moderate disease activity (2.6≤DAS28≤5.1) according to the EULAR recommendations for use in clinical practice.
Unchanged disease modifying anti rheumatic drug (DMARD) treatment (including unchanged dose) for at least 3 months or non-use of DMARDs, if applicable.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Already following a (near-)vegan diet.
Pregnancy.
Absolute contra-indication for exercise therapy: resting systolic blood pressure of >200 mmHg or diastolic blood pressure of >115 mmHg, acute myocardial infarction within the last 3 months, chest pain at rest/before exercise, other severe cardiac diseases (e.g. symptomatic aortic stenosis, severe cardiac arrhythmias).
Underweight (BMI<18,5 kg/m2).
In case of smoking, unwillingness to stop smoking for at least the duration of the study.
Low e-health competencies (lowest proficiency according to Pharos quick scan, see appendix B).
Insufficient comprehension of Dutch language.
Inability to be scheduled for therapy or meetings.
Concurrent presence of other forms of joint disease than OA, RA or ACPA positive arthralgia.
Psychiatric disease.
Total arthroplasty of hip or knee scheduled.
No informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-05-2019
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
This clinical trial will be registered on the website of the ‘Nederlands Trial Register’, the PhD thesis will be published online, including access to data upon request.
The investigators have the intention to publish the results in a scientific journal.

Ethische beoordeling

Positief advies

Datum:	17-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55868
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7800
CCMO	NL66649.029.18
OMON	NL-OMON55868

Resultaten

Samenvatting resultaten
not applicable yet