Plants for Joints RA

No registrations found.

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

Summary

ID

NL-OMON19881

Source
Nationaal Trial Register

Brief title
Plants for Joints RA

Health condition

Rheumatoid arthritis

Sponsors and support

Primary sponsor: Reade, Duyvensz-Nagel Stichting, Dr. Jan van Breemen Stichting, Stichting Vermeer 14, ZonMw
Source(s) of monetary or material Support: Own/private sources & public sources (ZonMw)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

General:
Self-reported physical (fatigue, pain intensity, pain interference, physical function, sleep disturbance), mental (anxiety, depression) and social (ability to participate in social roles & activities) health using the validated Dutch-Flemish Patient Reported Outcomes Measurement Information System (PROMIS®). This system uses computer adaptive testing (CAT) methods to evaluate physical, mental and social health. With CAT PROMIS® is able the dynamically select items based upon the respondent's previous answers. With this method measurement is limited to 3-7 questions to obtain valid outcomes (109).

Body composition & metabolism:
Body weight (with clothes, no shoes, kg)
Body height (cm)
BMI (kg/m2)
Waist circumference (cm, at approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest).
Total fat free mass (DEXA, kg & % of body weight)
Total muscle mass (DEXA, kg & % of body weight)
Total fat mass (DEXA, kg & % of body weight)

Physical performance:
Hand grip strength (dynamometer, kg/force), measured as the maximum grip score of 6 trials (3 left, 3 right), with the subject encouraged, in a seated position, forearms rested on the arms of the chair, wrist just over the end of the arm of the chair, in a neutral position, thumb facing upwards, feet flat on the floor, alternating sides (112).
Function (get-up-and-go test [GUG-test], seconds), measured as the time needed by the subject to get up from a chair without using the hands and to walk as fast as possible to a line 15.2 meters away from the chair (113).
Physical activity level (PAL, as coefficient related to base metabolic rate [BMR]), measured with a pedometer.

Metabolic:
Blood pressure (mmHg)
Heart rate variability, performed at baseline, at 4 months and at the end of the extension study. Measured by a 5-minute electrocardiography (ECG) in supine position and a 2-minute ECG during an orthostatic stress test.
Lipid profile (total cholesterol, LDL, HDL, triglycerides in blood, mmol/l)
Fasting glucose (blood, mmol/l)
HbA1c (blood, mmol/mol))

Pathogenesis:
Rheumatoid factor (RF, ACPA positive arthralgia patients for all measurements, RA patients only at baseline and at the end of the one-year extension study, blood)
Dominance of B-cell receptor clones (ACPA positive arthralgia patients, at baseline, 4 months and at the end of the extension year)
Erythrocyte sedimentation rate (ESR, component of DAS28)
Gut microbiota composition (faeces, colony forming units [CFU]/g), collected by the subject at home using an in-house collection kit, frozen, transferred to Reade and brought to -80o C at

Reade within 24 hours for later analysis.
Saliva microbiota composition (saliva, CFU/g), collected by the subject at home using an in-house collection kit, frozen, transferred to Reade and brought to -80o C at Reade within 24 hours for later analysis. A short questionnaire will be used to determine self-reported oral health.
Metabolome change (blood and urine, percentage change from baseline), collected during measurement visits at Reade and frozen at -80o C for later analysis. Later analysis of microbiome and metabolome samples (including measurement of short chain fatty acids) will be based on the at that time state of the art methods.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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).

Contacts

Public
Reade
Wendy Walrabenstein

+31658869219
Scientific
Reade
Wendy Walrabenstein

+31658869219

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-05-2019
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

Ethics review

Positive opinion

Date:	17-06-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55868
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
not applicable yet