Exercise in patients with Rheumatoid Arthritis and Cardiovascular risks

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The overall hypothesis is that the developed exercise therapy program is feasible, safe and improves cardiorespiratory fitness, functional performance, reduces CV risk factors and disease activity in patients with RA and high CV risk.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26383

Bron
NTR

Verkorte titel
the eRAC study

Aandoening

Rheumatoid Arthritis, Cardiovascular disease, Exercise therapy, Inflammation, Cardiorespiratory fitness, Reumatoïde Artritis, Cardiovasculaire ziekte, Oefentherapie, Ontsteking, Cardiorespiratoire fitheid

Ondersteuning

Primaire sponsor: Reade Center of Rehabilitation and Rheumatology
Overige ondersteuning: self-financing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome of the study is cardiorespiratory fitness assessed with a graded exercise tolerance test on an exercise bike (Lode, the
Netherlands).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Rheumatoid arthritis (RA) is associated with increased overall mortality compared to the general population, with cardiovascular diseases (CVD) as one of the main causes. The optimization of management of CV risk in RA patients is an important aim in the treatment. Active counseling is indispensable, including also attention to exercise, particularly in RA patients with a high CV risk, defined as a 10-year CV risk of 20% or higher. Physical exercise for these patients is necessary and challenging since professionals should take multiple factors into account, such as comorbid conditions related to CV risk (e.g. hypertension, diabetes mellitus and obesity). However, the effects of exercise therapy on CV risk in RA patients are unknown and the required intensity is also unknown.

Objectives:

The first aim of the present study is to develop a tailor-made exercise therapy program for these complex patients. The second aim is to evaluate the effect of exercise therapy in a pilot study on cardiorespiratory fitness and several secondary outcomes (i.e. safety, functional performance, CV risk factors, and disease activity).

Study design:

An experimental pre-posttest within-study design.

Study population:

Study population: 30 consecutive patients with RA recruited from an existing RA cohort with known risk factors.

Main study parameters/endpoints:

Primary outcome of the study is cardiorespiratory fitness assessed with a graded exercise tolerance test, either on a treadmill or an exercise bike (Lode, the Netherlands).

Secondary outcomes are functional performance, CV risk factors and disease activity.

Doel van het onderzoek

The overall hypothesis is that the developed exercise therapy program is feasible, safe and improves cardiorespiratory fitness, functional performance, reduces CV risk factors and disease activity in patients with RA and high CV risk.

Onderzoeksopzet

before and after the intervention outcomes wil be assessed

Onderzoeksproduct en/of interventie

The exercise therapy program will include exercises that are primarily aimed at improving cardiorespiratory fitness and functional performance in RA patients. Frequency, intensity, time, type and progression of the exercises will be performed according to the ACSM guideline (Durnstine 2009)

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Diagnosis of RA fulfilling the ACR/EULAR classification criteria, high 10-year CV risk (≥20%) calculated with the Dutch SCORE table, age >20 and <80 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Comorbidity which severely affects functional ability (CIRS≥2), K&L grading of ≥3 for hip and/or knee OA, contra-indication for exercises according to the ACSM guideline (Durnstine 2009) i.e., progressive increase in heart failure symptoms, myocardial infarction less than 3 months before the start of the training program, severe ischemia of the cardiac muscle upon exertion, respiratory frequency of more than 30 breaths per minute and heart rate at rest >110 bpm, insufficient control of the Dutch language and/or cognitive problems.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2017
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

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	NL6538
NTR-old	NTR6726
CCMO	NL 00000.000.00 METC

Resultaten

Samenvatting resultaten
Journals of rheumatology