

Subtypes Overweight and Rheumatoid Arthritis for (more) personalized care

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Research questions: To what extent does the subtype determined by means of the questionnaire (including algorithm) correspond with the subtype determined by a TCM expert?

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23194

Bron

NTR

Verkorte titel

Subtypes_ObRa

Aandoening

Overweight / obesity and rheumatoid arthritis

Ondersteuning

Primaire sponsor: none

Overige ondersteuning: For the sub-study Subtypes RA, a KIEM HBO subsidy has been awarded from SIA, National Agency for Practice-oriented Research (part of NWO).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Introduction. Chronic conditions are a common problem in the Netherlands. In 2019, half of the population had at least one chronic condition and 30% more than one chronic condition. A relatively large group are rheumatic diseases, including rheumatoid arthritis (RA). One factor contributing to the development of multiple chronic conditions is the prevalence of overweight and obesity. A healthy and active lifestyle has a positive influence on obesity, the symptoms of RA, limitations and quality of life. There is more and more evidence that people with the same condition can have other underlying causes, which means that lifestyle advice and interventions also differ from each other. These so-called subgroups can be identified in various ways, including blood and urine tests and examination by a systems biologist (eg an expert in Traditional Chinese Medicine). Both methods are time consuming and expensive. The aim of this study is to investigate the validity of two specific symptom questionnaires for subtyping overweight people on the one hand and people with RA on the other. The research question is: To what extent does the subtype determined by means of the questionnaire (including algorithm) correspond with the subtype determined by a TCM expert? Method. In this cross-sectional study, a distinction is made between two sub-studies with two target groups: (1) overweight / obese adults and (2) adults with RA. 50 participants are included in both studies.

The overweight subjects are recruited from the general population via the website (www.vitalelimburgers.nl), facebook and instagram, via participants of the 'Healthy Life' program, via the self-help group obesity (Zelfregietool.nl) and the Katholieke Bond Elderly (KBO). The subjects with RA are recruited via the rheumatology department of the VieCuri Medical Center and via the website (www.vitalelimburgers.nl). In addition, participants from previous studies are approached who have given permission for this. Potential subjects will receive the recruitment letter for this study by email or mail, including the contact details of the researchers.

Within both studies (overweight / obesity and RA), the data is collected digitally and online by means of:

1. Digital questionnaire about personal data (for example age, gender, BMI, number of years of rheumatoid arthritis, comorbidity, medication use) and the specific symptom questionnaire with yes / no questions to determine the subtype
2. Video interview, in which the subtype is determined during an anamnesis / interview with an expert (external criterion).

To determine the criterion validity, it is investigated to what extent the results from the relevant questionnaire and the results from the interview correspond, expressed in a correlation coefficient ($r \geq 0.8$ is assessed as "good" and used as a cut-off point). In addition, the sensitivity and specificity are assessed by means of a 2x2 table. In a ROC curve, the sensitivity of the test (true positives) on the y axis is plotted against the false positives (1

specificity) on the x axis at different cut-off values.

Doel van het onderzoek

Research questions: To what extent does the subtype determined by means of the questionnaire (including algorithm) correspond with the subtype determined by a TCM expert?

Onderzoeksopzet

n.a. / cross sectional study

Onderzoeksproduct en/of interventie

non

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

(1) overweight / obese adults Body Mass Index ≥ 25 ; and (2) adults with RA, diagnosed by a rheumatologist

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Not able to read and speak Dutch

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-06-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	18-05-2021
Soort:	Eerste indiening

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	NL9484
Ander register	METC Z; metc@zuyderland.nl : METCZ20210078

Resultaten