

Subtypes Overweight and Rheumatoid Arthritis for (more) personalized care

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23194

Source

NTR

Brief title

Subtypes_ObRa

Health condition

Overweight / obesity and rheumatoid arthritis

Sponsors and support

Primary sponsor: none

Source(s) of monetary or material Support: For the sub-study Subtypes RA, a KIEM HBO subsidy has been awarded from SIA, National Agency for Practice-oriented Research (part of NWO).

Intervention

Outcome measures

Primary outcome

criterion validity

Secondary outcome

none

Study description

Background summary

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.

Study objective

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?

Study design

n.a. / cross sectional study

Intervention

non

Contacts

Public

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Not able to read and speak Dutch

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	18-05-2021
Application type:	First submission

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
NTR-new	NL9484
Other	METC Z; metc@zuyderland.nl : METCZ20210078

Study results