

Self monitoring in rheumatoid arthritis using a smartphone app

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(1) patient self-monitoring is not inferior to standard of care in terms of DAS 28 score; (2) patient self-monitoring in RA patients will reduce outpatient clinic visits, and will consequently decrease healthcare costs.

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

Samenvatting

ID

NL-OMON24094

Bron

Nationaal Trial Register

Verkorte titel

SeMoRa-3

Aandoening

Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: None

Overige ondersteuning: AbbVie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

DAS 28 & Number of outpatient clinic visits

Toelichting onderzoek

Achtergrond van het onderzoek

Rising health care costs, increasing elderly population and shortage of personnel force us to think about alternative ways to organize our health care system. Telemedicine with self measurement of disease activity could be one of the key ingredients of the health care system of the future. The SeMoRa-3 study is a single blinded randomized controlled trial (RCT) in which patients with Rheumatoid Arthritis (RA) monitor their own disease activity with the help of a smartphone application. Patients randomized to the intervention group receive instructions, a username and a password for the MijnReumaReade smartphone app. They are instructed to complete weekly questionnaires and one outpatient clinic visit is planned at the end of the trial period. Additional follow up visits are scheduled on the basis of flares as recognized by the app or at the requests of individual patients. Patients in the standard care group continue their routine follow up visits as deemed necessary by the rheumatologist. Ultimately, the hypothesis is that after one year the disease activity is the same in both groups and the health care utilization will decline in the intervention group.

Doel van het onderzoek

(1) patient self-monitoring is not inferior to standard of care in terms of DAS 28 score;
(2) patient self-monitoring in RA patients will reduce outpatient clinic visits, and will consequently decrease healthcare costs.

Onderzoeksopzet

First inclusion may 2019, all patients included 2nd quarter 2020, all patients completed study 2nd quarter of 2021.

Addendum: due to the COVID-19 outbreak inclusion was stopped in april 2020 at 103 patients. With the new power analyses the non-inferiority limit has been set to 0.5. The study will have been completed by all patients by the end of april in 2021.

Onderzoeksproduct en/of interventie

Self-monitoring of disease activity combined with self initiated care

Contactpersonen

Publiek

Reade

Bart Seppen

020-2421806

Wetenschappelijk

Reade

Bart Seppen

020-2421806

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosed with RA by a rheumatologist
- Disease duration of at least 2 years
- Low disease activity or remission (DAS28 < 3,2) at moment of inclusion
- Taking a disease-modifying anti-rheumatic drug (DMARD)
- Own a mobile device with an Android or iOS operating system (implying mobile phone literacy)
- At least 18 years old
- Able to read and speak Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Medication change: start or stop of a DMARD (biologicals, or conventional DMARDS*) in the last 6 months.
- Is taking part in another intervention study

* Methotrexate, cyclosporine, cyclophosphamide, gold injections, hydroxychloroquine, leflunomide, mycophenolate, sulfasalazine, corticosteroids.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-06-2019
Aantal proefpersonen:	176
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:	07-05-2019
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

NTR-new

Ander register

ID

NL7715

METC Vumc : 2018.646

Resultaten

Samenvatting resultaten

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