Self monitoring in rheumatoid arthritis using a smartphone app

No registrations found.

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

Summary

ID

NL-OMON24094

Source
Nationaal Trial Register

Brief title
SeMoRa-3

Health condition

Rheumatoid Arthritis

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: AbbVie

Intervention

Outcome measures

Primary outcome

DAS 28 & Number of outpatient clinic visits

Secondary outcome

Patient satisfaction (10-point Likert scale), patient empowerment (Effective consumer scale),

Disease activity (Rapid 3), Treatment satisfaction (TSQM-9), medication adherence (CQR5), Healthcare Participation (WPAI), Overall Costs (Tic-P), Adherence (Questionnaire completion rates), Qualitative Data, App usability (System Usability Scale)

Study description

Background summary

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.

Study objective

(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.

Study design

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.

Intervention

Self-monitoring of disease activity combined with self initiated care

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2019
Enrollment:	176
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-05-2019
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	NL7715
Other	METC Vumc : 2018.646

Study results

Summary results

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