The SeMoRA-3 study. Self-monitoring in rheumatoid arthritis: the implementation of a digital care platform using smartphone technology for monitoring of disease activity.

Published: 11-04-2019
Last updated: 09-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON49364

Source
ToetsingOnline

Brief title
SeMoRA-3

Condition

- Joint disorders

Synonym
rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Abbvie,AbbVie B.V.

Intervention

Keyword: ehealth, rheumatoid arthritis, selfmonitoring, smartphone

Outcome measures

Primary outcome

* health care utilization as measured by the mean number of outpatient clinic visits with a rheumatologist during the 12 months trial period.

* disease activity as measured by the mean DAS28 at 12 months

Secondary outcome

* Health care satisfaction on a 10 point scale as recommended by the Institute for Healthcare Improvement. 38 Using any number from 0 to 10, where 0 is the worst health care possible and 10 is as the best health care possible, what number would you use to rate all your health care in the last 12 months?*

* Patient empowerment as measured by the Effective Consumer scale (EC-17)

* Disease activity as measured by Routine Assessment of Patient Index Data (RAPID3)

* Patient-physician interaction as measured by the Perceived Efficacy in Patient-Physician Interactions Questionnaire (PEPPI)

* Treatment satisfaction as measured by the Treatment Satisfaction Questionnaire for Medication (the TSQM questionnaire)

* Medication adherence as measured by the CQR5 Compliance Questionnaire Rheumatology (CQR5)

* Participation as measured by Work Productivity and Activity Impairment Questionnaire (WPAI)

* Overall costs of health care utilization including medication use and number of telephone appointments with a rheumatology health care professional as measured by a detailed questionnaire and retrieved from the Reade EMR

* Treating physician satisfaction as measured by a physician visit and exit form

* Qualitative data derived from focus group discussions at the end of the trial period

* Exploratory analysis on the causes of flares

* completion rates of weekly surveys as proxies for patient engagement and overall feasibility.

* system usability score (SUS)

Study description

Background summary

Rising health care costs, increasing elderly population and shortage of personel forces us to think about alternative ways how 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. It has been shown, for instance in inflammatory bowel disease, to empower patients to take care of their own health and reduce outpatient clinic visits.

Study objective

The overall objective of this proposal is to implement a digital care platform to monitor rheumatoid artritis disease activity between scheduled rheumatologist visits over 12 months. The essential components in this system are as follows:
(1) the MijnReuma Reade App,
(2) integration with the Reade Electronic Medical Record (EMR)
(3) a preprogrammed algorithm to identify increases in disease activity to

support self-management and self-initiated care
(4) personalized information regarding self-management of disease activity.

Study design

This is a single blinded pragmatic randomized controlled trial (RCT) of a digital care platform. The study design is similar to the telemedicine study in inflammatory bowel disease by de Jong et al. published in the Lancet in 2017.Participants randomized to the intervention group receive instructions, a username and a password for the app. Participants will use the App for 12 months and are instructed to complete a weekly questionnaire through the App and plan at least one routine outpatient visit during 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 (*usual care*), with an opportunity to schedule an extra visit if symptoms relapse.

Intervention

The digital care platform as described in the objective.

Study burden and risks

Patients will be seen twice (at T0 and T12 months) at the rheumatology outpatient clinic, and the visits will be combined as much as possible with regular visits. During these visits the burden consists of:
- undergoing physical examination of the joints
-filling out a questionnaire.
-regular venapunction to determine the disease activity score DAS28 and medication control, (ESR, CRP, Hb, Leucocytes, Thrombocytes, ALAT en kreatinin)

At 3,6 and 9 months, patients will complete a (digital) questionnaire at home

The risks of the examination, venapuntion and the questionnaire are minimal

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

To be included in this study, participants must:
* be diagnosed with rheumatoid arthritis by a rheumatologist
* have a disease duration of at least 2 years
* be in low disease activity or remission (DAS28 < 3,2) at moment of inclusion
* be taking a disease-modifying antirheumatic drug (DMARD)
* own a mobile device with an Android or iOS operating system
* be at least 18 years old
* be able to read and speak Dutch

Exclusion criteria

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-05-2019
Enrollment:	103
Type:	Actual

Medical products/devices used

Generic name:	MijnReuma Reade App
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-04-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL67704.029.19